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8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA
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11 IN RE: MCKINSEY & CO., INC.
12 NATIONAL PRESCRIPTION OPIATE
CONSULTANT LITIGATION

Case No. 21-md-02996-CRB (SK)

MASTER COMPLAINT (NAS)

13 This Document Relates to:

REDACTED

14 ALL NAS ACTIONS
15

JURY TRIAL DEMANDED

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1 **I. PREAMBLE**

2 This Complaint is an administrative device as described in *In re Propulsid Prods. Liab.*
 3 *Litig.*, 208 F.R.D.133, 142 (E.D. La. 2002) for the specific purposes of enabling the Court to
 4 address the threshold issues it articulated in its statements and Orders to date, and does not
 5 supersede the complaints filed in the individual actions consolidated in this multi-district
 6 litigation for pretrial proceedings only. *See Gelboim v. Bank of Am.*, 574 U.S. 405, 413 n.3
 7 (2015).

8 This Complaint does not necessarily include every claim asserted in every NAS action
 9 transferred to this MDL, nor is it intended to consolidate for trial the separate claims of the
 10 Plaintiffs included. This Complaint does not include every plaintiff-specific fact alleged in the
 11 underlying complaints, including facts related to individual damages. Some Plaintiffs styled their
 12 underlying complaints as class actions; this Master Complaint is not styled as a class action, but
 13 its filing does not waive any argument that class treatment of NAS claims may be appropriate.
 14 This Complaint incorporates by reference the complaints filed by individual NAS Plaintiffs
 15 pending in this MDL as of November 22, 2021.

16 Plaintiffs Melissa Barnwell, Andria Meeder, Jacqueline Ramirez, Andrew and Beverly
 17 Riling, Juliana Valdez, and Shelly Whittaker, each on behalf of their minor children, have not
 18 previously filed actions against the Defendants. These Plaintiffs respectfully request that this
 19 Master Complaint be deemed their original complaint under the direct-file provisions of PTO 7.

20 This Complaint does not concede that a federal court has subject matter jurisdiction over
 21 any Plaintiff's case or claim where that Plaintiff filed a timely motion to remand. Any properly-
 22 made objections to removal are preserved.

23 **II. INTRODUCTION**

24 1. For more than two decades, the opioid crisis has raged across this country. An
 25 opioid-related public health emergency was declared by the President in 2017. Last year was the
 26 worst on record, with drug overdoses soaring nearly 30%.¹ Today, there are increasingly few

27 _____
 28 ¹ Betsy McKay, "U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids," *Wall Street Journal*, July 14, 2021, available at: <https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200>.

1 Americans whose lives have not been affected by the consequences of opioid dependency,
2 addiction, and overdoses.

3 2. McKinsey is a management consulting firm with operations across the globe. It
4 played a central role in the unfolding, propagation, and exploitation of the opioid crisis by
5 advising multiple opioid manufacturers and other industry participants how to sell as many
6 opioids as conceivably possible. Knowing that its clients' products were highly addictive,
7 ineffective, and unsafe for the treatment of long-term chronic pain, non-acute pain, and non-
8 cancer pain, McKinsey developed a singular focus on increasing opioid sales, no matter the
9 resultant cost to society. McKinsey did this for well over a decade, despite knowing full well the
10 risk to public health and safety and the widespread economic harm from developing and
11 implementing the transformation of strictly-controlled substances into top-selling blockbuster
12 drugs.

13 3. The purpose of McKinsey's work with its opioids clients was at all times to
14 maximize return on investment. The whole point for those clients (and hence McKinsey) was to
15 make as much money as possible. They all did. This relentless drive to increase sales and create
16 greater availability of opioids was made with no concern about the parallel, known, and inevitable
17 increase in opioid-related deaths, addiction, abuse, diversion, and misuse.

18 4. In the world of management consulting, McKinsey is preeminent. It is one of the
19 world's oldest, largest, and most lucrative consulting firms and is generally seen as the most
20 prestigious firm in the industry. More consiglieri than one-off advisor, McKinsey touts its model
21 of engaging in "transformational partnerships" with its clients. McKinsey learns each client's
22 business intimately, embeds itself into all levels of the corporate hierarchy, and provides granular
23 strategies to achieve transformative goals for its clients.

24 5. Marvin Bower, the managing director of McKinsey from 1950 to 1967, was "the
25 father of the consulting profession."² He "turned the business of selling management advice into a
26 keystone of American corporate culture," and is "credited with taking a fledgling industry and
27

28 ² Douglas Martin, *Marvin Bower, 99; Built McKinsey & Co.*, N.Y. Times, Jan. 24, 2003, available at:
<https://www.nytimes.com/2003/01/24/business/marvin-bower-99-built-mckinsey-co.html>

1 setting its course not only as to the kinds of services it could sell but also the standards it must
 2 uphold for its work to be respected.”³ A lawyer by trade, Bower stressed that management
 3 consulting should be seen as an emergent profession, akin to the law or accounting, with
 4 obligations to clients and to the broader society that extend beyond the mere commercial.

5 6. Bower instilled an ethos at McKinsey that has been reinforced throughout the
 6 decades as a core value of the firm: “Deliver the bad news if you must, but deliver it properly.”⁴
 7 Bower’s principles, and the values he imparted within McKinsey, are said to guide the firm to the
 8 present day. “In many ways, certainly in spirit and soul, Marvin continued to lead it after he
 9 retired, and he leads it still,” eulogized Rajat Gupta, McKinsey’s then-global managing partner, at
 10 Bower’s funeral in 2003.⁵

11 7. This case is, in large part, about the firm’s failure to adhere to Bower’s simple,
 12 foundational tenet. It arises instead from the firm’s steadfast and continual work to maximize
 13 opioid sales in partnership with numerous clients during the pendency of the worst man-made
 14 epidemic in modern medical history. It is about McKinsey never delivering the “bad news” of
 15 opioids’ devastating impact on Plaintiffs and the public, properly or otherwise, and instead
 16 looking the other way for money.

19 ³ *Id.*

20 ⁴ Duff McDonald, *The Firm* 35 (2014).

21 ⁵ *Id.* at 270. In many ways, Gupta was an interesting figure to opine on Bower’s legacy. Indeed, Gupta’s leadership of
 22 McKinsey is in many respects to be *contrasted* with Bower’s legacy. Many of the values Bower emphasized—an
 23 emphasis on professionalism over commercial exploitation, for example—were jettisoned under Gupta’s tenure as
 24 managing partner of the firm, which ended in 2003. “Under his watch, McKinsey began to chase top billings in a way
 25 it never had before.” *Id.* at 234. For instance, McKinsey first began accepting equity stakes in clients as a form of
 26 incentive compensation during Gupta’s tenure. Previously, McKinsey only charged standard fees for its consulting
 27 services as Bower disdained the notion of taking equity stakes in clients. *Id.* at 234. Under Gupta, McKinsey also
 28 began to allow consultants’ compensation to be tied to client performance. *Id.*

Consistent with Gupta’s efforts to monetize McKinsey’s consulting business in ways previous firm
 leadership had not, McKinsey also began to expand its client base. “While the firm would never admit as much,
 under Gupta, McKinsey began working for just about anyone with a fat bank account and a checkbook.” *Id.* at 266.

Institutions age, and by the time Gupta came to lead the firm in 1994, McKinsey was a mature institution. It
 had built up significant value in its *reputation* by historically advising *only* “blue chip” companies “at the top of the
 corporate pyramid.” *Id.* Under Gupta, McKinsey began the process of realizing that value. For McKinsey, the way to
 monetize an elite reputation was to start advising those it historically may have shunned as clients—to start offering
 its *imprimatur*, in addition to its services, for money. McKinsey’s work with opioid manufacturers began under
 Gupta’s leadership.

1 8. When it came to opioids, McKinsey did far more than just give advice. Not only
2 did it suggest courses of action that its clients should adopt, the firm remained in place and
3 worked collaboratively alongside its clients to actually implement McKinsey's recommendations
4 to achieve objectives jointly identified by the clients and McKinsey. McKinsey stood alongside
5 its clients in the arena doing the deeds.

6 9. The deceptive marketing strategies that McKinsey and its clients invented,
7 developed, deployed, and continually refined for years to expand the market for opioids are
8 foundational to the epidemic.

9 10. McKinsey worked hand-in-hand with major opioid manufacturers, including
10 Purdue Pharma L.P., Endo Pharmaceuticals,⁶ Johnson & Johnson,⁷ and Mallinckrodt⁸ for years.
11 At the same time, McKinsey advised other participants in the opioid supply chain, including
12 distributors, pharmacies, and even regulators.

13 11. In particular, McKinsey advised the Sackler family and their company, Purdue, for
14 years while Purdue aggressively marketed OxyContin, widely viewed as the taproot of the opioid
15 crisis. The relationship began no later than 2004. In the years following Purdue's 2007 guilty plea
16 for misleadingly marketing OxyContin, McKinsey continued to work closely with Purdue to
17 dramatically increase OxyContin sales, notwithstanding the existence of a five-year Corporate
18 Integrity Agreement that Purdue entered as part of its guilty plea.

19 12. McKinsey knew of the dangers of opioids and in particular the prior misconduct of
20 Purdue but nonetheless advised Purdue and other opioid manufacturers to improperly market and
21 sell OxyContin and other prescription opioids, supplying granular sales and marketing strategies
22 and remaining intimately involved throughout implementation of those strategies. McKinsey's
23 actions resulted in a surge in sales of OxyContin and other opioids that fueled and prolonged the
24 opioid crisis.

25
26
27 ⁶ "Endo Pharmaceuticals" or "Endo" refers to Endo Health Solutions Inc., Endo International plc, and Endo
Pharmaceuticals Inc., collectively.

28 ⁷ "Johnson & Johnson" refers to Johnson & Johnson Services, Inc. and its wholly-owned subsidiary Janssen
Pharmaceuticals, Inc. ("Janssen").

⁸ "Mallinckrodt" refers to Mallinckrodt LLC and Mallinckrodt plc, together.

13. For years, McKinsey advised Purdue on, designed, and helped to implement various strategies to raise sales of OxyContin by focusing on high dose sales and deceptively messaging to physicians that OxyContin would improve function and quality of life. For example, McKinsey urged Purdue to maximize sales by dictating, to a greater degree, which prescribers its sales representatives would target, exploring ways to increase the amount of time those sales representatives spent in the field increasing opioid sales and prioritizing OxyContin in incentive compensation targets.⁹

14. McKinsey's partnership with Purdue reached its fever pitch in the summer of 2013. In January of that year, Purdue's Corporate Integrity Agreement expired, and Purdue was no longer bound by its constraints. Within months, the Sacklers tasked McKinsey with transforming Purdue's approach to OxyContin sales in order to extract as much money as possible from the remaining patent life of the drug.¹⁰

15. In response, McKinsey developed and proposed Project Turbocharge, a series of transformational changes that McKinsey proposed to implement at Purdue to dramatically increase OxyContin sales by re-tooling Purdue's sales force and investing large amounts of capital to "turbocharge" it. "[O]ur recommendation is that Purdue makes a clear go-no-go decision to 'Turbocharge the Sales Engine'," McKinsey told Purdue on August 8, 2013.

16. The Sacklers chose "go," and McKinsey subsequently implemented and continually refined Project Turbocharge at Purdue over the course of years, to devastating, but profitable, effect.

17. McKinsey has recently been the subject of scrutiny for its various business practices, including its work facilitating the opioid crisis with Purdue.¹¹ On March 7, 2019, Kevin Sneader, McKinsey's then-global managing partner, addressed all McKinsey employees regarding this scrutiny. Drawing inspiration from Theodore Roosevelt, Sneader stated,

⁹ PPLPC012000437346

¹⁰ OxyContin, like any branded pharmaceutical, is subject to eventual patent expiration and competition from generic opioid manufacturers.

¹¹ See Michael Forsythe and Walt Bogdanich, *McKinsey Advised Purdue Pharma How to 'Turbocharge' Opioid Sales, Lawsuit Says*, N.Y. Times, Feb. 1, 2019, available at: <https://www.nytimes.com/2019/02/01/business/purdue-pharma-mckinsey-oxycontin-opioids.html>.

1 [W]e cannot return to a time when we were in the background and unobserved.
 2 Those days have gone. Indeed, I have little doubt that scrutiny—fair and unfair—
 3 will continue. It is the price we pay for being “in the arena” and working on what
 4 matters.¹²

5 18. Weeks later, McKinsey announced that it would no longer work for any opioid
 6 manufacturer. “Opioid abuse and addiction are having a tragic and devastating impact on our
 7 communities. We are no longer advising clients on any opioid-specific business and are
 8 continuing to support key stakeholders working to combat the crisis.”¹³

9 19. The price for being in the arena is more than mere scrutiny. McKinsey is liable for
 10 its misconduct and the harms it caused or exacerbated. McKinsey is liable for its successful
 11 efforts to increase opioid sales for years. It continued this work unabated and with alacrity despite
 12 events as stunning as Purdue’s 2007 guilty plea for misbranding OxyContin, Purdue’s 2015
 13 settlement with the State of Kentucky, and numerous other enforcement actions related to opioid
 14 sales and marketing by McKinsey clients. Through it all, McKinsey remained steadfast in its
 15 efforts to promote opioid sales for all of its clients for the purpose of maximizing return on
 16 investment without regard to the obvious implications of what they were doing. Indeed, the firm

17
 18 ¹² See “The Price We Pay for Being ‘In the Arena’”: McKinsey’s Chief Writes to Staff About Media Scrutiny and
 19 Scandal, Fortune Magazine, March 8, 2019, available at <https://fortune.com/2019/03/08/mckinsey-staff-letter-kevin-sneader/>. The “arena” reference is to *Citizenship in a Republic*, a speech delivered by Theodore Roosevelt at the
 20 Sorbonne on April 23, 1910:

21 It is not the critic who counts; not the man who points out how the strong man stumbles, or where
 22 the doers of deeds could have done them better. The credit belongs to the man who is actually in the
 23 arena [here, McKinsey; and the arena, opioid sales], whose face is marred by dust and sweat and
 24 blood; who strives valiantly; who errs, who comes short again and again, because there is no effort
 without error and shortcoming; but who does actually strive to do the deeds; who knows great
 enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in
 the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring
 greatly, so that his place shall never be with those cold and timid souls who neither know victory
 nor defeat.

25 As it happens, Mr. Sneader is not the only McKinsey person to draw inspiration from Roosevelt. *Citizenship*
 26 *in a Republic* similarly inspired Dominic Barton, the man Mr. Sneader succeeded as McKinsey’s global managing
 27 partner. It served as the basis for his 2017 address to the Ivey Business School in Canada. See Dominic Barton *In the*
 28 *Arena: Leadership in an Age of Disruption*, October 17, 2017, available at: https://www.ivey.uwo.ca/media/3780710/daquino_lecture2017.pdf. While McKinsey continues to preach the values of corporate integrity from the
 Bower area, its actions show that it has moved far afield from its professed moral compass.

¹³ See Paul La Monica, *Consulting firm McKinsey no longer working with opioid maker Purdue Pharma*, CNN, May
 24, 2019, available at: <https://www.cnn.com/2019/05/24/business/mckinsey-purdue-pharma-oxycontin/index.html>.
 The statement was attributed to McKinsey as an entity. No individual’s name was attributed.

endeavored alongside its clients to increase the size of the *overall* opioid market for *nearly two decades*, until as late as March 22, 2019, despite increasingly blood-red flags along the way.¹⁴

III. JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action for the reasons stated in each underlying complaint.

21. This Court has personal jurisdiction over McKinsey for the reasons stated in each underlying complaint.

22. Venue is appropriate for pretrial proceedings under *In re McKinsey & Co., Inc., Nat'l Prescription Opiate Consultant Litig.*, MDL No. 2996, 2021 WL 2351628 (J.P.M.L. June 7, 2021).

IV. PARTIES

A. NAS Plaintiffs

23. Plaintiffs are minor children born with neonatal abstinence syndrome (“NAS”) resulting from their exposure to opioids in the womb and subsequent withdrawal (collectively, “Minor Plaintiffs”) and their legal guardians.

24. Melissa Barnwell on behalf of her natural minor children, E.G. and C.G., all residents of Visalia, CA. Ms. Barnwell’s opioid prescriptions were prescribed and filled in California, where E.G. and C.G. were born. Absent direct filing, Plaintiffs would have filed in the Eastern District of California.

25. Hayden Travis Blankenship, on behalf of his natural minor child, Z.D.B.B., both residents of Peterstown, WV. Upon information and belief, Z.D.B.B.’s biological mother’s opioid prescriptions were prescribed and filled in West Virginia, where Z.D.B.B. was born.

26. Marina Brizendine on behalf of her natural minor child, S.B., both currently residents of Chandler, TX. At all relevant times, Ms. Brizendine and S.B. lived in Kentucky. Ms. Brizendine’s opioid prescriptions were prescribed and filled in Kentucky, where S.B. was born.

¹⁴ See “About McKinsey’s past work for opioid manufacturers,” *last updated March 22, 2021*, available at: <https://www.mckinseyopioidfacts.com> (“We decided nearly two years ago to end all work on opioid-specific business”)

1 27. Lisa Renee Daniels on behalf of her legally adopted minor child, A.K.D., both
2 residents of Charleston, WV. Upon information and belief, A.K.D.'s biological mother's opioid
3 prescriptions were prescribed and filled in West Virginia, where A.K.D. was born.

4 28. April Hudak, on behalf of her natural minor child, H.S., both residents of Golden,
5 CO. Ms. Hudak's opioid prescriptions were prescribed and filled in Colorado, where H.S. was
6 born.

7 29. Timothy Lambert, on behalf of his natural minor children, T.J.L. and M.L., all
8 residents of Beckley, WV. Upon information and belief, T.J.L. and M.L.'s biological mother's
9 opioid prescriptions were prescribed and filled in West Virginia, where T.J.L. and M.L. were
10 born.

11 30. Andria Meeder, on behalf of her natural minor child C.M., both residents of
12 Fredonia, NY. Ms. Meeder's opioid prescriptions were prescribed and filled in New York, where
13 C.M. was born. Absent direct filing, Plaintiffs would have filed in the Western District of New
14 York.

15 31. Jacqueline Ramirez on behalf of her natural minor child, R.R., both residents of
16 Oxnard, CA. Ms. Ramirez's opioid prescriptions were prescribed and filled in California, where
17 R.R. was born. Absent direct filing, Plaintiffs would have filed in the Central District of
18 California.

19 32. Beverly and Andrew Riling, on behalf of their legally adopted minor child, A.R.,
20 all residents of Pineville, WV. Upon information and belief, A.R.'s biological mother's opioid
21 prescriptions were prescribed and filled in West Virginia, where A.R. was born. Absent direct
22 filing, Plaintiffs would have filed in the Southern District of West Virginia.

23 33. Julieann Valdez on behalf of her natural minor children, J.V. and M.V., all
24 residents of Las Vegas, NV. Ms. Valdez's opioid prescriptions were prescribed and filled in Utah,
25 where J.V. was born. By the time Ms. Valdez moved to Nevada, where M.V. was born, she was
26 already dependent on opioids. Under the proposed direct-filing provision, Plaintiffs indicate they
27 would have filed in the Southern District of New York.
28

1 34. Anita Whigham on behalf of her legally adopted minor child, J.C., both residents
2 of Menomonee Falls, WI. J.C.'s biological mother's opioid prescriptions were prescribed and
3 filled in Wisconsin, where J.C. was born.

4 35. Shelly Whittaker on behalf of her natural minor children, E.W., N.G., and G.O., all
5 residents of Colorado Springs, CO. Ms. Whittaker's opioid prescriptions were prescribed and
6 filled in Colorado, where G.O., N.G., and E.W. were born. Absent direct filing, Plaintiffs would
7 have filed in the Southern District of New York.

8 36. Cynthia Woolwine, on behalf of her natural minor children, B.W. and E.G.W., all
9 residents of Oceana, WV. On information and belief, Ms. Woolwine's opioid prescriptions were
10 prescribed and filled in West Virginia, where B.W. and E.G.W. were born.

11 **B. Defendants**

12 37. Defendant McKinsey & Company, Inc. is a corporation organized under the laws
13 of the state of New York. McKinsey's principal place of business is located at 711 Third Avenue,
14 New York, NY 10017. It may be served with process via its registered agent, Corporation Service
15 Company, at 80 State Street, Albany, NY 12207.

16 38. Defendant McKinsey Holdings, Inc. is a Delaware corporation with its principal
17 place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with
18 process via its registered agent, Corporation Service Company, 251 Little Falls Drive,
19 Wilmington, DE 19808

20 39. Defendant McKinsey & Company, Inc. United States is a Delaware corporation
21 with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may
22 be served with process via its registered agent, Corporation Service Company, 251 Little Falls
23 Drive, Wilmington, DE 19808

24 40. Defendant McKinsey & Company, Inc. Washington D.C. is a Delaware
25 corporation with its principal place of business is located at 711 Third Avenue, New York, NY
26 10017. It may be served with process via its registered agent, Corporation Service Company, 251
27 Little Falls Drive, Wilmington, DE 19808.

41. Upon information and belief, McKinsey & Company, Inc. is the parent company of McKinsey & Company Holdings, Inc., which is itself the parent company of both McKinsey & Company, Inc. United States and McKinsey & Company, Inc. Washington D.C. Upon information and belief, each subsidiary corporation is wholly-owned by its parent. Despite the corporate form, McKinsey began as a partnership and still refers to its senior employees as “partners.” Those partners are the firm’s shareholders. Collectively, these four Defendants are referenced throughout as “McKinsey.”

42. McKinsey is a global management consultancy with offices in over 130 cities in 65 countries, including the following United States cities: Atlanta, GA; Austin, TX; Houston, TX; Dallas, TX; San Francisco, CA; Los Angeles, CA; Redwood City, CA; Boston, MA; Charlotte, NC; Chicago, IL; Cleveland, OH; Denver, CO; Detroit, MI; Miami, FL; Miramar, FL; Tampa, FL; Minneapolis, MN; Summit, NJ; New York, NY; Philadelphia, PA; Pittsburgh, PA; Seattle, WA; St. Louis, MO; Stamford, CT; Waltham, MA; and Washington, D.C.

43. McKinsey is registered to do business in all fifty states.

V. FACTUAL ALLEGATIONS APPLICABLE TO ALL CLAIMS

A. The Opioid Crisis

44. The term “opioid” refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

45. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

46. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left

1 with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the
2 United States, and many doctors prescribed opioids solely to prevent their patients from suffering
3 withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in
4 1911: "The habit has this nation in its grip to an astonishing extent Our prisons and our
5 hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and
6 made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of
7 unhappiness and sin in the United States."

8 47. Pharmaceutical companies have long tried to develop substitutes for opium and
9 morphine that would provide the same analgesic effects without the addictive properties. In 1898,
10 Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of
11 morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and
12 cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in
13 the United States was limited to prescription only in 1914 and then banned altogether a decade
14 later.

15 48. Although heroin and opium became classified as illicit drugs, there is little
16 difference between them and prescription opioids. Prescription opioids are synthesized from the
17 same plant as heroin, have similar molecular structures, and bind to the same receptors in the
18 human brain.

19 49. Due to concerns about their addictive properties, prescription opioids have usually
20 been regulated at the federal level as Schedule II controlled substances by the Drug Enforcement
21 Administration since 1970.

22 50. Throughout the twentieth century, pharmaceutical companies continued to develop
23 prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally
24 produced in combination with other drugs, with relatively low opioid content.

25 51. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern
26 opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths:
27 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin
28

1 delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen
2 times that.

3 52. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's
4 OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and
5 Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide
6 continuous opioid therapy for, in general, twelve hours. Short-acting opioids, such as Cephalon's
7 Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic
8 pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid
9 therapy lasting approximately four to six hours. Still other short-term opioids, such as Insys's
10 Subsys, are designed to be taken in addition to long-acting opioids to specifically address
11 breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The
12 opioid manufacturers promoted the idea that pain should be treated by taking long-acting opioids
13 continuously and supplementing them by also taking short-acting, rapid-onset opioids for
14 episodic or "breakthrough" pain.

15 53. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As
16 tolerance increases, a patient typically requires progressively higher doses in order to obtain the
17 same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the
18 "high." However, opioids depress respiration and, at very high doses, can, and often do, arrest
19 respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term
20 opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

21 54. Discontinuing opioids after more than just a few weeks of therapy will cause most
22 patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety,
23 nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and
24 other serious symptoms, which may persist for months after a complete withdrawal from opioids,
25 depending on how long the opioids were used.

26 55. As one doctor put it, the widespread long-term use of opioids "was an experiment
27 on the population of the United States. It wasn't randomized, it wasn't controlled, and no data
28 was collected until they started gathering death statistics."

1 56. The results were devastating, and the nation continues to reach ever grimmer
2 milestones. In 2020, drug-overdose deaths in the United States soared nearly 30%, reaching all-
3 time highs.¹⁵

4 **B. Marketing and the Origins of the Opioid Crisis**

5 57. OxyContin, manufactured by Purdue Pharma L.P., was introduced to the market in
6 1996. Within six years of its introduction, the increasingly widespread misuse and abuse of
7 OxyContin and similar opioids had drawn the attention of the United States Senate.

8 58. Two decades ago, Dr. Art Van Zee traveled from the rural coal town of St.
9 Charles, in the southwestern corner of Virginia, to Washington D.C. to provide testimony to the
10 United States Senate Committee on Health, Education, Labor and Pensions. On February 12,
11 2002, that Committee held a hearing entitled “Examining the Effects of the Painkiller OxyContin,
12 Focusing on Federal, State, and Local Efforts to Decrease Abuse and Misuse of this Product
13 While Assuring Availability for Patients Who Suffer Daily from Chronic Moderate to Severe
14 Pain.”¹⁶

15 59. Today, OxyContin—and the methods used to sell it—is widely seen as a principal
16 taproot of the opioid crisis. In those early days of the unfolding opioid epidemic, Dr. Van Zee’s
17 medical practice in St. Charles put him in a position to offer informed, first-hand observations of
18 the toll that the pharmaceutical industry’s efforts to market opioids was exacting from his
19 community. He testified:

20 In the 25 years I have practiced as a general internist in St. Charles, which is a small
21 Appalachian coal mining town, there has never been anything to compare to the
22 epidemic of drug abuse and addiction that we have seen the last 3 years with
23 OxyContin. Contrary to what is sometimes portrayed in the media as long-term
24 addicts switching to the drug *du jour*, what we have seen for the most part is
25 numerous young people recreationally using OxyContin and then becoming very
rapidly addicted. Many of these kids are good kids, good families with bright,
promising futures that are being destroyed in every way by their opioid addiction.¹⁷

26 ¹⁵ Betsy McKay, “U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids,” *Wall*
27 *Street Journal*, July 14, 2020, *available at*: <https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200>.

28 ¹⁶ A transcript of the hearing is *available at*: <https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>

¹⁷ *See* <https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>

1 60. Further, Dr. Van Zee identified the sales and marketing practices of the
2 pharmaceutical industry when selling controlled substances as a primary cause of the problem:

3 My own personal view of the complicated OxyContin abuse problem is that there
4 are at least three major elements involved. First, there has been an obvious problem
5 with physician misprescribing and overprescribing of this drug. Second, this
6 epidemic has been a vicious indicator of the alarming degree of prescription drug
7 abuse in our society. *Third and perhaps the one closest to this committee and the
FDA is that the promotion and marketing of OxyContin by Purdue Pharma has
played a major role in this problem.*¹⁸

8 61. Five years after Dr. Van Zee's testimony and eighty miles from his hometown of
9 St. Charles, United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty
10 plea of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the
11 misbranding of OxyContin. Brownlee stated, "Even in the face of warnings from health care
12 professionals, the media, and members of its own sales force that OxyContin was being widely
13 abused and causing harm to our citizens, Purdue, under the leadership of its top executives,
14 continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive,
15 less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of
16 OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug
17 that Purdue led many to believe was safer, less subject to abuse, and less addictive than other pain
18 medications on the market."

19 62. Two years later, in 2009, Dr. Van Zee published *The Promotion and Marketing of*
20 *OxyContin: Commercial Triumph, Public Health Tragedy* in the American Journal of Public
21 Health.

22 63. In his paper, Dr. Van Zee stated the matter plainly: "Compared with noncontrolled
23 drugs, controlled drugs, with their potential for abuse and diversion, pose different public health
24 risks when they are overpromoted and highly prescribed."¹⁹ In one sense, Dr. Van Zee's
25 observation is not particularly novel. Indeed, it approaches tautology: controlled substances are
26 *controlled* precisely because they should not be sold to maximize volume and profits. This did not

27 ¹⁸ *Id.* (emphasis added).

28 ¹⁹ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*,
American Journal of Public Health, February 2009, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>

1 prevent McKinsey and Purdue from marketing Purdue's opioids full hilt, however. By 2004,
 2 "OxyContin had become the most prevalent prescription opioid in the United States."²⁰

3 64. Dr. Van Zee identified the three principal marketing tactics Purdue employed as a
 4 source of OxyContin misuse and abuse—the exact tactics McKinsey identified and promoted—
 5 and suggested that regulation may be appropriate to curtail its use. The first was the use of
 6 granular sales and marketing data to profile individual prescribers and identify those that already
 7 prescribe large amounts of opioids. "Through these profiles, a drug company can identify the
 8 highest and lowest prescribers of particular drugs on a single zip code, county, state, or the entire
 9 country. One of the critical foundations of Purdue's marketing plan for OxyContin was to target
 10 the physicians who were the highest prescribers for opioids across the country."²¹

11 65. The second tactic was the use of incentive compensation structures to encourage
 12 the salesforce to sell ever more prescriptions of OxyContin. Bonuses at Purdue were "uncapped,"
 13 meaning there was no upper limit to what an OxyContin salesperson could earn. Rather,
 14 salesforce remuneration was a direct function of overall OxyContin sales—the more you sell, the
 15 more you make. "A lucrative bonus system encouraged sales representatives to increase sales of
 16 OxyContin in their territories, resulting in large numbers of visits to physicians with high rates of
 17 opioid prescriptions, as well as a multifaceted information campaign aimed at them."²²

18 66. The third tactic was to increase the overall number of individual calls that the
 19 salesforce placed to prescribers. "From 1996 to 2000, Purdue increased its internal sales force
 20 from 318 sales representatives to 671, and its total physician call list from approximately 33,400
 21 to 44,500 to approximately 70,500 to 94,000 physicians."²³

22 67. When combined, these tactics produced the intended result. "The use of prescriber
 23 profiling data to target high-opioid prescribers—coupled with very lucrative incentives for sales
 24 representatives—would seem to fuel increased prescribing by some physicians—perhaps the most
 25 liberal prescribers of opioids and, in some cases, the least discriminate."²⁴

26 ²⁰ *Id.*

27 ²¹ *Id.*

28 ²² *Id.*

²³ *Id.*

²⁴ *Id.*

68. Dr. Van Zee’s observations regarding the direct link between OxyContin marketing and overall opioid overdose mortality would, in time, be confirmed by further academic work, including empirical research published by the National Bureau of Economic Research in 2019.

69. McKinsey played a central role in the sales and marketing of these Schedule II controlled substances in the United States for many years. Throughout that time, the purpose of McKinsey’s actions was singular: making the most money possible no matter the resultant cost to society. Indeed, no significant concern was given to the fact that greater availability of drugs correlates to opioid-related deaths, addiction, abuse, and misuse. Return on investment was McKinsey’s guiding light. McKinsey partnered with numerous opioid manufacturers and other opioid industry participants to maximize the return on investment in sales and marketing efforts for numerous opioid products, and did so contemporaneously. Despite the fact that the Schedule II controlled substances were designed for a small, narrowly defined group—patients with acute, terminal, or cancer-related pain—McKinsey’s goal, in all instances, was to sell as many pills as conceivably possible.

C. What McKinsey Does: “Consulting is more than giving advice.”

70. McKinsey is a global consulting firm with many areas of expertise, including the pharmaceutical industry. As a management consulting firm, McKinsey provides plans to managers, directors, and owners on how to run their companies or other enterprises, and helps implement those plans.

71. Management consulting is the business of providing solutions to clients. Solutions take many forms, depending on the client’s needs. “Management consulting includes a broad range of activities, and the many firms and their members often define these practices quite differently.”²⁵

72. Broadly speaking, there are two schools of management consulting. “Strategy” consulting provides big-picture advice to clients about how they approach their business: how the

²⁵ Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, available at: <https://hbr.org/1982/09/consulting-is-more-than-giving-advice>

1 business is structured, which markets to compete in, potential new business lines, and mergers
 2 and acquisitions. The strategy consultant provides a plan to the client that the client may choose
 3 to adopt or not.

4 73. “Implementation” consulting is what comes next. If strategy consulting is
 5 providing advice to a client, “implementation” work is what happens once the client has adopted
 6 the consultant’s plan. After a client has adopted the strategy consultant’s recommendations, the
 7 implementation consultant remains in place with the client to actually do the necessary work and
 8 execute on the plan.

9 74. In his 1982 *Harvard Business Review* article entitled “Consulting is More Than
 10 Giving Advice,” Professor Arthur Turner of the Harvard Business School described the then-
 11 current state of the consulting industry’s attitude toward implementation work:

12 The consultant’s proper role in implementation is a matter of considerable debate in
 13 the profession. Some argue that one who helps put recommendations into effect
 14 takes on the role of manager and thus exceeds consulting’s legitimate bounds.
 15 Others believe that those who regard implementation solely as the client’s
 16 responsibility lack a professional attitude, since recommendations that are not
 17 implemented (or implemented badly) are a waste of money and time. And just as
 the client may participate in diagnosis without diminishing the value of the
 consultant’s role, so there are many ways in which the consultant may assist in
 implementation without usurping the manager’s job.²⁶

18 75. Although McKinsey has historically been regarded as a “strategy” consulting firm,
 19 by the time it was working with Purdue, implementation services were a core component of the
 20 suite of services that McKinsey provided within the “transformational relationship” it developed
 21 with its clients.²⁷ Indeed, writing in 2013, Harvard Business School Professor Clayton
 22 Christensen observed the decline in “pure” strategy work performed by consultants, as the
 23 industry sought to diversify its income streams by offering implementation and other services to
 24 clients. “For example, at traditional strategy-consulting firms, the share of work that is classic
 25
 26

27 ²⁶ *Id.*

28 ²⁷ For McKinsey’s own description of its implementation services, See <https://www.mckinsey.com/business-functions/mckinsey-accelerate/how-we-help-clients/implementation> (last accessed October 19, 2020).

1 strategy has been steadily decreasing and is now about 20%, down from 60% of 70% some 30
2 years ago.”²⁸

3 76. When partnering with clients, a core component of the McKinsey relationship is
4 discretion. “The basis of any client relationship with the firm is trust. Companies share their most
5 competitive secrets with McKinsey with the understanding that confidentiality is paramount.
6 McKinsey consultants aren’t even supposed to tell their own spouses about their client work.”²⁹
7 McKinsey recognizes it must have its clients’ trust and make confidentiality “paramount,” as
8 “[c]ompanies share their most competitive secrets with McKinsey” for McKinsey to do its
9 work.³⁰

10 77. During the implementation phase, McKinsey essentially bonds with the client.
11 Describing McKinsey’s approach to implementation, one McKinsey consultant stated, “In some
12 of the most successful engagements I’ve seen, you can’t even tell the difference between a
13 McKinsey team member and one of our clients because we working that cohesively together.”³¹

14 78. Another McKinsey Senior Implementation Coach described McKinsey’s
15 approach: “We’re in there interacting with every element of that organization, from the welders or
16 mechanics on the front line, all the way up to the board of directors.”³²

26 ²⁸ Clayton Christensen, Dina Wang, and Derek van Bever, “Consulting on the Cusp of Disruption,” *Harvard*
27 *Business Review*, October 2013, available at <https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption>

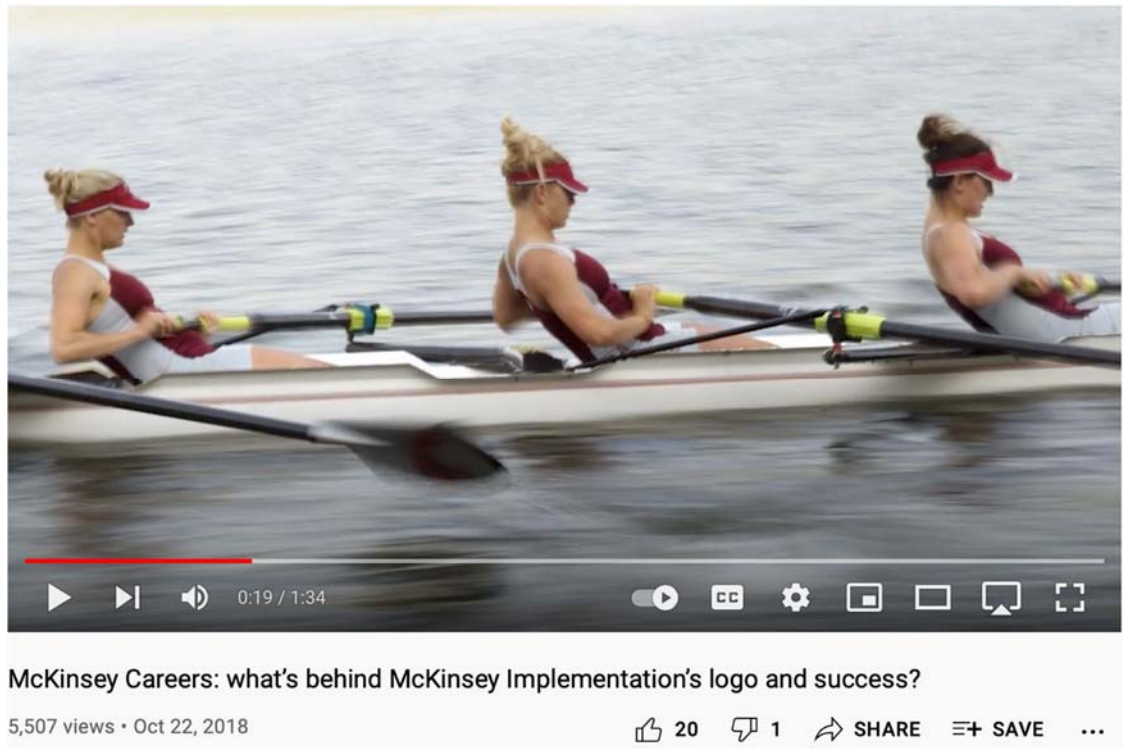
27 ²⁹ McDonald, *The Firm*, Pg. 308.

28 ³⁰ *Id.* at 308.

28 ³¹ McKinsey on Implementation, April 30, 2017, available at <https://www.youtube.com/watch?v=rEQOGVpl9CY>

³² *Id.*

79. McKinsey's implementation team even has a symbol: a rowing team.



80. Jenny, a Practice Manager at McKinsey, explained its significance: “The rowers symbolized to us being in the boat with the clients, doing real work and being jointly responsible for the success.”³³

81. Eugene, a partner, further offered:

The reason McKinsey implementation works is because clients love it. The fact that we are staying longer with them, the fact that we're getting in to the trenches, the fact that we are there to walk the emotional journey with them when they're going through the tough times and really changing their companies, is what makes McKinsey implementation truly distinctive.³⁴

82. In the broadest of generalities, then, McKinsey's business model, as a provider of strategy and implementation consulting services, is to partner with clients to pursue business objectives identified by McKinsey. Once an objective is identified, the client and McKinsey then engage in concerted action as a seamless and cohesive unit in order to implement the necessary means to achieve it.

³³ See “McKinsey Careers: what's behind McKinsey Implementation's logo and success?”, October 22, 2018, available at <https://web.archive.org/web/20200419140214/https://www.youtube.com/watch?v=3-Zx859VJtw>

³⁴ *Id.*

1 **1. McKinsey’s Long-Term Partnership with the Pharmaceuticals**
 2 **Industry**

3 83. Today, McKinsey’s website explains “How We Help Clients” in the
 4 pharmaceuticals industry: “Helping clients maximize commercial value by assisting with product
 5 launch, marketing, sales, and market access.”³⁵ McKinsey helps numerous clients throughout the
 6 pharmaceutical industry, from manufacturers to distributors and pharmacies. It often does so
 7 contemporaneously. For instance, McKinsey might advise multiple opioid manufacturers on the
 8 sales and marketing of competing branded opioid products.

9 84. McKinsey’s dominance of the consulting space in the pharmaceutical industry
 10 presents its own opportunity for further client service. Specifically, McKinsey also helps its
 11 clients by telling them what their competitors—who are also McKinsey clients—are doing.

12 85. For example, McKinsey pitched its services to Purdue on the basis that it was able
 13 to “*bring examples from other successful companies*” and perform “detailed analytics.”³⁶

14 **2. The McKinsey Pharmaceuticals and Medical Products Practice Group**

15 86. Like most management consulting companies, McKinsey organizes itself into
 16 practice groups that specialize in a given industry.

17 87. McKinsey has long maintained a Pharmaceuticals and Medical Products (“PMP”)
 18 industry practice group dedicated to working with pharmaceutical companies. In 2004, when
 19 McKinsey’s relationship with Purdue began, the PMP group was led by Michael Pearson. Pearson
 20 worked for McKinsey for twenty-three years and was a member of the firm’s shareholder council
 21 (McKinsey’s equivalent of a board of directors) in addition to leading PMP before departing
 22 McKinsey in 2008 to helm Valeant Pharmaceuticals.³⁷

23
 24
 25
 26 ³⁵ <https://www.mckinsey.com/industries/life-sciences/how-we-help-clients/commercial>

27 ³⁶ PPLPC021000601208 (emphasis added).

28 ³⁷ John Gapper, *McKinsey’s fingerprints are all over Valeant*, Financial Times, March 23, 2016, available at:
<https://www.ft.com/content/0bb37fd2-ef63-11e5-aff5-19b4e253664a>

Notably, Rob Rosiello, a McKinsey partner who was a Director of Client Services (or “DCS”) of the Purdue
 account alongside co-DCS’es Maria Gordian and Martin Elling, went on to join Pearson at Valeant in 2015 as Chief
 Financial Officer. The DCS is the partner in charge of the client account.

1 88. Pearson stated: “At McKinsey pharmaceuticals was one of our biggest industry
2 groups.”³⁸ Pearson was “not the quintessential suave and intellectual McKinsey partner. He was
3 loud and profane and was seen, in the words of one former colleague, as ‘sharp-edged and sharp
4 elbowed.’”³⁹

5 89. Under his leadership, McKinsey’s knowledge and expertise in the pharmaceutical
6 industry was significant. By 2009, McKinsey described its capabilities: “We have an unparalleled
7 depth of both functional and industry expertise as well as breadth of geographical reach. Our
8 scale, scope, and knowledge allow us to address problems that no one else can. At heart, we are a
9 network of people who are passionate about taking on immense challenges that matter to leading
10 organizations, and often, to the world.”

11 90. In 2012, while advising Purdue, McKinsey described PMP and its health care
12 capabilities thusly: “Indeed, there is a doctor in the house. We have more than 1,700 consultants
13 with significant healthcare experience, including more than 150 physicians and 250 consultants
14 with advanced degrees in genetics, immunology, biochemical engineering, neurobiology, and
15 other life sciences. We also have 75 consultants with advanced degrees in public health,
16 healthcare management, and related fields.”

17 91. That same year, the PMP group published a report entitled “Death of a Sales
18 Model, or Not: Perspectives on the Evolution of Pharmaceutical Field Based Selling.”⁴⁰ In it,
19 McKinsey partner Laura Moran co-authored a segment called “The Few, The Proud, The Super-
20 Productive: How a ‘smart field force’ can better drive sales.” In the segment, Moran and her co-
21 authors described various ways a pharmaceutical company could optimize its sales force. Moran
22 worked on the Purdue account, where the strategies outlined in her article were incorporated into
23 Project Turbocharge two years later.

24
25 ³⁸ Michael Peltz, *Mike Pearson’s New Prescription for the Pharmaceuticals Industry*, Institutional Investor,
26 September 3, 2014, *available at*: <https://www.institutionalinvestor.com/article/b14zbjfm8nf1c4/mike-pearsons-new-prescription-for-the-pharmaceuticals-industry>

27 ³⁹ John Gapper, *McKinsey’s fingerprints are all over Valeant*, Financial Times, March 23, 2016, *available at*:
<https://www.ft.com/content/0bb37fd2-ef63-11e5-aff5-19b4e253664a>

28 ⁴⁰ “Death of a Sales Model, or Not,” Pharmaceutical and Medical Product Practice, McKinsey, *available at*
https://www.mckinsey.com/~media/mckinsey/dotcom/client_service/pharma%20and%20medical%20products/pmp%20new/pdfs/2012%20death%20of%20a%20sales%20model%20or%20not.pdf

92. With respect to pharmaceutical marketing, the PMP group states, “We support clients in creating high-impact strategies that maximize value, using customized tools. We also have detailed market data for all major geographic regions.”⁴¹ PMP also works with pharma clients regarding their sales force: “Our efforts span the entire organization—we can help train and restructure sales forces, work directly in the field to provide coaching, maximize value from back-office services, develop strategies to accelerate short-term sales, and assist with company-wide commercial transformations.”⁴²

93. McKinsey has long considered itself a “leadership factory” for good reason.⁴³ Nowhere is this more apparent than the pharmaceutical industry, where, thanks to PMP’s efforts under Pearson’s leadership, McKinsey continues to reign as the dominant management consultant.

94. Consistent with PMP’s ambition that McKinsey be the dominant consultant in the pharmaceutical industry, McKinsey has blanketed the entire pharmaceutical supply chain with alumni.

95. Rajiv de Silva, for instance, was appointed CEO of Endo Pharmaceutical in March 2013. Endo’s two top-selling drugs were pain medications. Endo—and de Silva, individually—have been named in multiple lawsuits related to the ongoing opioid crisis. Previously, de Silva worked with Pearson in a leadership position within PMP at McKinsey before joining Rob Rosiello, a former McKinsey partner, and Pearson at Valeant.⁴⁴ McKinsey advised Endo on its opioid business.

96. Likewise, Frank Scholz was a partner at McKinsey and a leader in the PMP group for seventeen years prior to departing in 2013 to join Mallinckrodt, another opioid manufacturer presently in bankruptcy after being named in numerous lawsuits relating to the ongoing opioid crisis. In fact, Scholz was the President of the “Specialty Generics” division of Mallinckrodt

⁴¹ See <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/commercial>

⁴² *Id.*

⁴³ See Adam Jones, “Should business schools fear McKinsey’s leadership factory?,” *Financial Times*, May 22, 2016, available at: <https://www.ft.com/content/0d17f670-1612-11e6-b197-a4af20d5575e>

⁴⁴ David Sell, “Endo CEO downplays Valeant link,” *Philadelphia Inquirer*, November 5, 2015, available at https://www.inquirer.com/philly/business/20151106_Endo_CEO_downplays_Valeant_link.html

1 (formerly SpecGX LLC), which is the division that sold generic opioids. McKinsey advised
2 Mallinckrodt on its opioid business.

3 97. Teva Pharmaceuticals,⁴⁵ another opioid manufacturer named in numerous lawsuits
4 for its role in the opioid crisis, is led by President and Chief Executive Officer and McKinsey
5 alumnus, Kare Schultz. He joined the company in 2017, at which point he was also appointed to
6 Teva's board of directors. Through an asset manager named Deerfield, McKinsey's in-house
7 hedge fund held a financial stake in Teva Pharmaceuticals while McKinsey advised its numerous
8 clients on how to maximize opioid sales.⁴⁶

9 98. McKinsey's involvement with Teva has been long-term. In 2006, upon his
10 retirement from McKinsey, Roger Abravanel joined Teva's board of directors the following
11 year.⁴⁷ By 2011, Teva had acquired Cephalon, Inc., another manufacturer of opioids, as "a core
12 part of [Teva's] strategy" of "growth through acquisitions."⁴⁸ Befitting the pattern, Cephalon had
13 its own long-standing ties to McKinsey before being acquired by Teva. In 2008, when Cephalon's
14 Executive Vice President, General Counsel, and Secretary John E. Osborn retired, he accepted a
15 job as "an advisor on life sciences regulatory and compliance matters to the international
16 consulting firm McKinsey & Company, Inc."⁴⁹

17 99. McKinsey has ties to another notable opioid industry combination: the 2012
18 acquisition of Actavis, Inc. by Watson Pharmaceuticals, Inc. ("Watson") for €4.25 billion. In the
19 aftermath of the acquisition of the large European pharmaceutical company, Watson created a
20 "Global Integration Management Office" reporting directly to its CEO, Paul Bisaro, to focus "on
21
22
23

⁴⁵ "Teva Pharmaceuticals" or "Teva" refers to Teva Pharmaceutical Industries Ltd. and Teva
24 Pharmaceuticals USA, Inc., together.

⁴⁶ Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from
25 treating addicts.," *NBC News*, February 8, 2021, *available at* <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>
26 McKinsey's in-house hedge fund is discussed further, below.

⁴⁷ Form 20-F dated December 31, 2012, Teva Pharmaceutical Industries Limited, *available at*
27 <https://www.sec.gov/Archives/edgar/data/818686/000119312513050510/d450498d20f.htm>

⁴⁸ *Id.*

⁴⁹ "Cephalon General Counsel John E. Osborn to Resign Position," February 8, 2008, *available at*
28 https://www.sec.gov/Archives/edgar/data/873364/000110465908008569/a08-5085_1ex99d1.htm

1 planning and implementing the integration of Actavis.”⁵⁰ In order to achieve this critical task,
 2 Watson hired Marc Lehn: “We were very pleased to recruit Marc from McKinsey & Company,
 3 Inc. to lead the Integration Management Office. Marc has years of experience in the generic
 4 industry and knows our culture and way of operating.”⁵¹ Notably, the press release indicates that
 5 McKinsey was already advising Watson regarding the acquisition: “*Although Marc does not*
 6 *formally join our Company until July*, he will nevertheless be involved in the integration planning
 7 during this interim period.”⁵²

8 100. Allergan,⁵³ another opioid manufacturer and defendant in the nationwide opioid
 9 litigation, has also relied on McKinsey as a source of management candidates. McKinsey Senior
 10 Adviser Christopher J. Coughlin joined Allergan’s board in 2014 and remains there today.

11 101. Abbott Labs, which partnered with Purdue in the early years of OxyContin to use
 12 Abbott’s sales force to market Purdue’s drug, has been led by CEO Miles White since 1998.
 13 White began his career at McKinsey around 1980.

14 102. As the preceding paragraphs make clear, McKinsey was in a truly unique position:
 15 given its dominance of pharmaceutical management consulting through PMP, practically all
 16 opioid industry participants were its clients. And those same clients routinely hire McKinsey
 17 consultants to leadership positions within their companies. While advising multiple industry
 18 participants regarding the sales of competing products, McKinsey was in a position to know
 19 confidential information and trade secrets of these clients “with the understanding that
 20 confidentiality is paramount.”⁵⁴

21 103. Because of its client relationships, McKinsey was, quite literally, the sole
 22 repository on Earth of this collective knowledge of industry-wide tactics regarding the sales and
 23 marketing of opioids, and the outcomes thereof. This unique collection of knowledge and
 24

25 _____
 26 ⁵⁰ “Watson Announces Formation of Global Integration Management Office to Support ending Actavis Acquisition,”
 PR Newswire, May 9, 2012, *available at* [https://www.prnewswire.com/news-releases/watson-announces-formation-](https://www.prnewswire.com/news-releases/watson-announces-formation-of-global-integration-management-office-to-support-pending-actavis-acquisition-150755565.html)
 27 [of-global-integration-management-office-to-support-pending-actavis-acquisition-150755565.html](https://www.prnewswire.com/news-releases/watson-announces-formation-of-global-integration-management-office-to-support-pending-actavis-acquisition-150755565.html)

⁵¹ *Id.*

⁵² *Id.* (emphasis added).

⁵³ Allergan is part of the same corporate family as Actavis and Watson.

⁵⁴ McDonald, *The Firm*, Pg. 308.

1 expertise made McKinsey a hub: even if any two given industry participants did not know what
2 each other was doing, McKinsey knew exactly what *both* were doing because both were clients.

3 104. McKinsey's relationships and influence carry far beyond the manufacturers. For
4 instance, current McKinsey director Nancy Killefer has also been an independent director of
5 Cardinal Health, Inc. ("Cardinal")—one of the "Big Three" Distributor Defendants in the
6 ongoing nationwide opioid litigation—since 2015. Chunhui Moi, Cardinal's current Vice
7 President of Corporate Strategy, was previously an associate principal at McKinsey, where he
8 worked for nine years. Michele Holcomb, Cardinal's current Executive Vice President, Chief
9 Strategy and Business Development Officer, was a partner in the Global Pharmaceutical Practice
10 at McKinsey.

11 105. McKinsey populates the "strategy" positions at the other opioid distributors as
12 well. At AmerisourceBergen, the "Director of Corporate Development and Strategy" was hired
13 away from McKinsey, where she had previously been a senior associate. AmerisourceBergen's
14 Executive Vice President and Chief Strategy Officer had previously been a partner at McKinsey.

15 106. At McKesson Corporation ("McKesson"), another McKinsey client, the President
16 of McKesson Specialty Health and, previously Vice President of Corporate Strategy, was Marc
17 Owen. "Prior to joining McKesson, Owen was a senior partner at McKinsey, advising
18 pharmaceutical manufacturers, healthcare providers, distributors and technology companies,
19 *including McKesson*, for more than a decade."⁵⁵ After Owen was promoted in 2012, McKesson
20 hired yet another Vice President of Corporate Strategy away from McKinsey.

21 107. In short, one way McKinsey adds value for a client is by knowing what all of its
22 competitors are doing. It possesses a greater body of knowledge about any given industry in
23 which it advises multiple participants than any individual participant does itself.

24 **3. The Transformational Relationship**

25 108. McKinsey has long touted the notion of a "transformational relationship." It is the
26 goal of every client relationship McKinsey develops and, McKinsey argues, the best way to

27
28 ⁵⁵ "Marc Owen Appointed President of McKesson Specialty Health," McKesson, January 31, 2012, *available at*
<https://www.mckesson.com/about-mckesson/newsroom/press-releases/2012/marc-owen-appointed-president-of-mckesson-specialty-health/> (emphasis added)

1 extract value from a client's use of McKinsey's services. McKinsey is not a one-off seller of
 2 advice for any given CEO's problem of the day. Rather, McKinsey argues that real value for the
 3 client derives from an ongoing "transformational" relationship with the firm.⁵⁶

4 109. At its core, the "transformational relationship" is *long-term*. It is the antithesis of a
 5 one-off contract wherein McKinsey performs one discreet project for a client and then concludes
 6 its business. Rather, "once McKinsey is inside a client, its consultants are adept at artfully
 7 creating a feedback loop through their work that purports to ease executive anxiety but actually
 8 creates more of it."⁵⁷ The long term result can be "dependence" on the McKinsey consultants.
 9 "We insinuate ourselves," Ron Daniel, McKinsey's then-managing partner, told *Forbes* in 1987.⁵⁸

10 110. "They have follow-on work not just because they're good at what they do, but
 11 because they are trained in how to manage these kinds of client relationships. They understand
 12 that the core reality is the relationship and the conversation, and that any particular engagement is
 13 merely epiphenomenal," explained Alan Kantrow, formerly the editor of *McKinsey Quarterly*.⁵⁹

14 111. This strategy of weaving itself into all aspects of its clients' business proved
 15 enormously successful for McKinsey over the years. It was a strategy McKinsey encouraged its
 16 consultants to take with clients to great effect:

17 The sell worked: Once ensconced in the boardrooms of the biggest corporate players
 18 in the world, McKinsey rarely left, ensuring a steady and growing flow of billings
 19 for years if not decades. In 2002, for example, *BusinessWeek* noted that at that
 20 moment, the firm had served four hundred clients for fifteen years or more.⁶⁰

22 ⁵⁶ Duff McDonald, *The Firm*, Pg. 136-37 ("McKinsey no longer pitched itself as a project-to-project firm; from this
 23 point forth [the late 1970s], it sold itself to clients as an ongoing prodger of change, the kind a smart CEO would
 keep around indefinitely.").

24 ⁵⁷ *Id.* at pg. 6. Purdue provides a fine example of this feedback loop in action. In 2008, when McKinsey was advising
 Purdue regarding Risk Evaluation and Mitigation Strategies ("REMS") for OxyContin required by the FDA,
 25 McKinsey partner Maria Gordian wrote to fellow partners Martin Elling and Rob Rosiello regarding progress in the
 "REMS work" as well as "Broader Strategy work." Regarding the latter, Gordian noted that Purdue board members
 Jonathan Sackler and Peter Boer "basically 'blessed' [Craig Landau] to do whatever he thinks is necessary to 'save
 26 the business.' . . . I believe there is a good opportunity to get another project here." MCK-MAAG-0117875
 (emphasis added). Indeed, after the REMS work was completed, McKinsey continued to work on "Broader Strategy
 27 work" for another decade.

28 ⁵⁸ John Merwin, "We Don't Learn from Our Clients, We Learn from Each Other," *Forbes*, October 19, 1987.

⁵⁹ Duff McDonald, *The Firm*, Pg. 185.

⁶⁰ *Id.* at pg. 136.

112. Another aspect of the transformational relationship McKinsey develops with clients is the development and marketing of “leave-behind” products, such as software applications, that are sold to clients as tools that can be used by the business on an on-going and recurring basis, separate and apart from McKinsey’s project-based consulting work. As described by Harvard Business School Professor Clayton Christensen, starting in 2007, “McKinsey & Company initiated a series of business model innovations that could reshape the way the global consulting firm engages with clients. One of the most intriguing of these is McKinsey Solutions, software and technology-based analytics and tools that can be embedded at a client, providing ongoing engagement outside the traditional project-based model.”⁶¹

113. McKinsey’s relationship with Purdue provides an example of the deployment of these “leave-behind” products. One McKinsey Solution is a pharmaceutical sales and marketing workforce optimization tool called FieldGuide, a proprietary software application McKinsey sells to clients. “The FieldGuide tool optimizes salesforce deployment and territory design through advanced geospatial analysis that leverages both market-potential insights across device categories and advanced sales-response curve analysis.”⁶² McKinsey sold it to Purdue for the purpose of optimizing Purdue’s OxyContin salesforce.

D. McKinsey and Purdue: A Case Study in Transformation

114. Indeed, McKinsey’s work with Purdue is a prime example of the transformational relationship in action. McKinsey counted Purdue as a client at least as early as 2004, three years *before* Purdue’s parent and officers first pleaded guilty to misbranding OxyContin in 2007. McKinsey was actively working with Purdue to increase OxyContin sales despite that guilty plea and continued to do so throughout the time period that Purdue and its advisors were bound by the terms of the Corporate Integrity Agreement entered in to alongside the guilty plea. McKinsey’s work with Purdue continued through at least 2018.

⁶¹ Clayton Christensen, Dina Wang, and Derek van Bever, “Consulting on the Cusp of Disruption,” *Harvard Business Review*, October 2013, available at <https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption>

⁶² <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/medtech/marketing-and-sales>

115. McKinsey staffed at least forty known consultants to Purdue, from senior partners all the way down through engagement managers and entry-level associates. Throughout the unfolding of the nationwide opioid crisis that only continued to worsen after the 2007 guilty plea, McKinsey remained steadfast alongside the Sacklers and Purdue every step of the way. The *mea culpas* would come only later.

116. McKinsey partner Maria Gordian, in her March 26, 2009 “EY 2009 Impact Summary” internal report to McKinsey director Olivier Hamoir and McKinsey’s Personnel Committee, recounted her accomplishments that year on the Purdue account. The document is an annual self-assessment produced by McKinsey partners. In it, Gordian described the state of firm’s relationship for Purdue:

With client work extending through the 3rd quarter, and several additional proposals in progress, we continue to expand the depth and breadth of our relationships at Purdue. We look forward to deepening our relationships with the Sackler family and serving them on key business development issues, and to expanding our relationship with [John] Stewart and other members of the senior management team.⁶³

117. Gordian even described herself as a counselor to Richard Sackler in the same memorandum, in addition to being a “point of contact for the Board and Sackler family.”⁶⁴

118. The continued expansion of the depth and breadth of McKinsey’s relationship with Purdue was an ever-present internal goal for McKinsey, as it was accompanied by recurring and ever-increasing client billings.

119. By 2014, both the breadth and depth of McKinsey’s relationship with Purdue had expanded dramatically. During the 2009 to 2014 period in particular, Purdue relied extensively on McKinsey to develop and implement its sales and marketing strategy for OxyContin. But McKinsey’s work for Purdue involved many other facets of Purdue’s business beyond sales and marketing, including general and administrative consulting, review of product acquisition, evaluation of research and development, advising Purdue on the design of clinical studies, risk management, and interactions with regulators.

⁶³ The Ad Hoc Group of Non-Consenting States’ Statement in Support of the Official Committee of Unsecured Creditors’ Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex 7, Pg. 48; MCK-MAAG 0118669.

⁶⁴ *Id.*

120. McKinsey's sales and marketing work for Purdue focused on creating and implementing strategies and tactics to bolster the sales of OxyContin, a Schedule II drug that is widely recognized as among the most frequently diverted and abused opioids. As Purdue faced growing scrutiny, McKinsey also helped the company protect its public image and profit from the market for illicit opioids, which McKinsey's industry-wide efforts helped to promote and maintain.

121. McKinsey understood the Sacklers' goals for Purdue and the work it would need to perform to maintain and grow Purdue's opioid profits amidst a growing epidemic of addiction and abuse. Part of McKinsey's work involved assessing the "underlying drivers" of OxyContin's (financial) performance. As described below, these drivers boil down to two things: (1) a widespread deceptive marketing campaign and (2) fueling an illicit market for non-medical use. Purdue entered into guilty pleas arising out of both types of conduct in 2007 and 2020, respectively. McKinsey delved into the "granular" aspects of Purdue's sales and promotion. And, throughout the two companies' long-term relationship, McKinsey understood Purdue's business "both in terms of content and culture," as its own renewed consulting agreement assured in 2013.

1. 2004: McKinsey and Purdue Meet

122. On March 1, 2004, McKinsey entered into a Master Consulting Agreement with Purdue for services that would be defined from time to time.⁶⁵ The Agreement was signed on McKinsey's behalf by Rob Rosiello, then a senior partner in the PMP practice group. After a ruling that held patents on OxyContin unenforceable due to Purdue misleading the patent office, McKinsey stepped in to help Purdue.⁶⁶

123. The Master Consulting Agreement [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁶⁷

[REDACTED]

⁶⁵ PPLPC012000069192

⁶⁶ *Id.*

⁶⁷ *Id.*

1 [REDACTED]
 2 [REDACTED]”⁶⁸
 3 124. From 2004 through 2008, McKinsey advised Purdue on research and development,
 4 business development, and product licensing related to Purdue’s opioid products.⁶⁹ Consistent
 5 with its business model, McKinsey leveraged these projects into growth of its “Broader Strategy
 6 work” also underway with Purdue.⁷⁰ Specifically, in October 2008, Purdue retained McKinsey for
 7 broad strategy work after two board members “blessed” Purdue executive Craig Landau with
 8 doing “whatever he thinks is necessary to ‘save the business’” after the 2007 criminal plea and
 9 introduction of generic competition to the older OxyContin.⁷¹

10 **2. 2007: Purdue Pleads Guilty to Misbranding OxyContin and is Bound**
 11 **by a Corporate Integrity Agreement**

12 125. On May 10, 2007, John Brownlee, United States Attorney for the Western District
 13 of Virginia, announced the guilty plea of the Purdue Frederick Company, the parent of Purdue
 14 Pharma, relating to the misbranding of OxyContin. Brownlee stated,

15 Even in the face of warnings from health care professionals, the media, and members
 16 of its own sales force that OxyContin was being widely abused and causing harm to
 17 our citizens, Purdue, under the leadership of its top executives, continued to push a
 18 fraudulent marketing campaign that promoted OxyContin as less addictive, less
 19 subject to abuse, and less likely to cause withdrawal. In the process, scores died as
 20 a result of OxyContin abuse and an even greater number of people became addicted
 21 to OxyContin; a drug that Purdue led many to believe was safer, less subject to
 22 abuse, and less addictive than other pain medications on the market.

23 126. Purdue Frederick Company as well as three of Purdue’s officers, pleaded guilty to
 24 the misbranding of OxyContin pursuant to various provisions of the Federal Food, Drug, and
 25 Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*

26 127. Purdue admitted that “supervisors and employees, with the intent to defraud or
 27 mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion,
 28 and less likely to cause tolerance and withdrawal than other pain medications.” Part of this

⁶⁸ PPLPC020000034087

⁶⁹ PPLPC013000116218; PPLP004401340

⁷⁰ MCK-MAAG-0117875

⁷¹ *Id.*

1 deceptive messaging included highlighting OxyContin as a long-acting (“LA”) or extended
 2 release (“ER”) opioid and suggesting it created less chance for addiction than “immediate
 3 release” opioids because it had fewer “peak and trough” blood level effects or “did not cause a
 4 ‘buzz’ or euphoria” in the same manner as these other opioids.

5 128. Concurrent with its guilty plea, Purdue entered into a Corporate Integrity
 6 Agreement with the Office of Inspector General of the United States Department of Health and
 7 Human Services on May 7, 2007. Purdue’s compliance obligations under the Corporate Integrity
 8 Agreement ran for a period of five years, and ultimately terminated in January 2013.⁷²

9 129. Pursuant to the Corporate Integrity Agreement, Purdue was obligated to implement
 10 written policies regarding its compliance program and compliance with federal health care
 11 program and Food and Drug Administration requirements, including:

12 a. “selling, marketing, promoting, advertising, and disseminating Materials or
 13 information about Purdue’s products in compliance with all applicable FDA requirements,
 14 including requirements relating to the dissemination of information that is fair and accurate . . .
 15 including, but not limited to information concerning the withdrawal, drug tolerance, drug
 16 addiction or drug abuse of Purdue’s products”;

17 b. “compensation (including salaries and bonuses) for Relevant Covered
 18 Persons engaged in promoting and selling Purdue’s products that are designed to ensure that
 19 financial incentives do not inappropriately motivate such individuals to engage in the improper
 20 promotion or sales of Purdue’s products”; and

21 c. “the process by which and standards according to which Purdue sales
 22 representatives provide Materials or respond to requests from [health care providers] for
 23 information about Purdue’s products, including information concerning withdrawal, drug
 24 tolerance, drug addiction, or drug abuse of Purdue’s products,” including “the form and content of
 25 Materials disseminated by sales representatives,” and “the internal review process for the
 26 Materials and information disseminated by sales representatives.”

27
 28 _____
⁷² See <https://www.justice.gov/opa/press-release/file/1329576/download>

130. Purdue was obligated to engage an Independent Review Organization to ensure its compliance with the strictures of the Corporate Integrity Agreement and to file compliance reports on an annual basis with the Inspector General.

131. In the wake of its accession to the Corporate Integrity Agreement, Purdue faced newly imposed constraints on its sales and marketing practices. The Corporate Integrity Agreement was a problem to solve. Despite the agreement's constraints (i.e., do not lie about OxyContin), Purdue and its controlling owners, the Sackler family, still intended to maximize OxyContin sales.

3. The Sacklers React to the "Concentration of Risk" Posed to Them by the Opioid Business.

132. The Sackler family has owned and controlled Purdue and its predecessors since 1952. At all times relevant to this Complaint, individual Sackler family members occupied either six or seven of the seats on Purdue's board of directors, and at all times held a majority of Board seats. To advise the board of directors of Purdue Pharma was to advise the Sackler family. The interests of the Sackler family and the Purdue board of directors, and Purdue itself, as a privately held company, were all aligned. Practically, they were indistinguishable.⁷³

133. As a result of the 2007 guilty plea, the Sacklers made the strategic decision to distance the family from Purdue, which was regarded, in the words of Richard Sackler, as an increasingly dangerous "concentration of risk" for Purdue's owners. Ten days after the guilty plea was announced, David Sackler wrote to his father, Richard Sackler, and uncle, Jonathan Sackler, describing precisely what that "risk" was: legal liability for selling OxyContin. In response to Jonathan stating that "there is no basis to sue 'the family,'" David replied:

⁷³ Craig Landau, soon to become CEO of Purdue, acknowledged in May 2017 that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." The future CEO of the company, in other words, understood that he would have little practical power despite his new title. The owners ran the business.

1 Message

2 From: David Sackler [REDACTED]
 3 Sent: 5/17/2007 11:08:08 PM
 4 To: 'Sackler, Jonathan' [REDACTED]; Sackler, Dr Richard [REDACTED]
 5 CC: Ives, Stephen A. [REDACTED]
 6 Subject: RE: Idea
 7 Attachments: image001.jpg

8 Well I hope you're right, and under logical circumstances I'd agree with you, but we're living in America. This is the land
 9 of the free and the home of the blameless. We will be sued. Read the op-ed stuff in these local papers and ask yourself
 10 how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten
 11 us.

12 134. Given concern over this "concentration of risk," the two sides of the Sackler
 13 family spent considerable time and energy debating the best way to achieve distance from Purdue,
 14 and collectively considered a variety of options for doing so. One option was to sell the company
 15 to or merge the company with another pharmaceutical manufacturer. They discussed Shire as a
 16 possible target, as were Cephalon, UCB, and Sepracor, Inc. The proceeds of such a transaction
 17 could then be re-invested in diversified assets, thereby achieving the Sacklers' desired distance
 18 from opioids.

19 135. Mortimer D.A. Sackler advocated for a sale or merger in a February 21, 2008
 20 email to Richard Sackler (a former president and co-chairman of Purdue) and several others,
 21 writing, "The pharmaceutical industry has become far too volatile and risky for a family to hold
 22 95% of its wealth in. It simply is not prudent for us to stay in the business given the future risks
 23 we are sure to face and the impact they will have on the shareholder value of the business and
 24 hence the family's wealth." The risk he referred to was, at least in significant part, further liability
 25 related to OxyContin.

26 136. Another option was to have Purdue borrow money in order to assure Purdue had
 27 adequate funds to continue operating while the Sacklers, as owners, began to make substantial
 28 distributions of money from the company to themselves. Once again, the proceeds of the
 distributions could then be re-invested in diversified assets, thereby achieving the Sacklers'
 desired distance.

137. In order to pursue either of these options, the Sacklers needed to maximize opioid
 sales in the short term so as to make Purdue—by then the subject of substantial public scrutiny—

1 appear either as an attractive acquisition target or merger partner to another pharmaceutical
2 manufacturer or as a creditworthy borrower to a lender.

3 138. In short, the Sacklers planned to engage in a final flurry of opioid pushing in order
4 to rid themselves of their pharmaceutical company dependency for good.

5 139. In fact, in the years after the 2007 guilty plea, Purdue would retain only the
6 absolute minimum amount of money within it as possible: \$300 million. Purdue was required to
7 retain that amount pursuant to a partnership agreement with separate company. Otherwise, all the
8 money was distributed to its owners.⁷⁴

9 140. Given the complexity of the problem, the Sacklers and Purdue realized that they
10 would need assistance in achieving these internally contradictory objectives. Purdue did not have
11 the capabilities in-house to design and implement a sales strategy for OxyContin that would
12 achieve the Sacklers' objectives. They turned to the global management consulting firm
13 McKinsey, which had already been advising the Sacklers and Purdue for at least three years, for
14 help with their new problem.

15 141. Notably, under the terms of Paragraph II.C.1(b) of the Corporate Integrity
16 Agreement, McKinsey, as a contractor to Purdue performing sales and marketing functions for
17 the company, was itself a "Covered Person" subject to the strictures of the Agreement.⁷⁵

18 **4. Purdue Tasks McKinsey with Boosting Opioid Sales in Light of the**
19 **Guilty Plea and Corporate Integrity Agreement.**

20 142. The Sacklers faced a problem: the need to grow OxyContin sales as dramatically
21 as possible so as to make Purdue an attractive acquisition target or borrower, while at the same
22 time appearing to comply with the Corporate Integrity Agreement. As one Purdue executive
23 stated of Purdue's attitude toward the Corporate Integrity Agreement: "They did not listen to their
24
25

26 ⁷⁴ See Jared S. Hopkins, *At Purdue Pharma, Business Slumps as Opioid Lawsuits Mount*, Wall Street Journal, June
27 30, 2019, available at: https://www.wsj.com/articles/purdue-pharma-grapples-with-internal-challenges-as-opioid-lawsuits-mount-11561887120?mod=hp_lead_pos6

28 ⁷⁵ The relevant language in the Corporate Integrity Agreement provides: "'Covered Persons' includes . . . all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions . . . on behalf of Purdue." PDD1712900096.

critics and insisted they had just a few isolated problems. After the settlement, they didn't change—the way the sales force was managed and incentivized, everything stayed the same.”⁷⁶

143. Purdue and the Sacklers were well aware of the constraints posed by the Agreement. Indeed, during a May 20, 2009 Executive Committee Meeting, the discussion led to whether Purdue should have a single sales force marketing all Purdue products, including OxyContin, or instead to “create a separate Sales Force for Intermezzo (a sleeping pill) that would be comprised of approximately 300 representatives.” John Stewart, Purdue's then-CEO, saw an opportunity, and asked if the Corporate Integrity Agreement would apply if Purdue were to launch Intermezzo and another Purdue product, Ryzolt (a branded version of Tramadol, another narcotic painkiller), using the separate sales force. Might the new drug launch fall outside of the Corporate Integrity Agreement, he asked?⁷⁷

144. It would not, he was told by Bert Weinstein, Purdue's Vice President of Compliance.⁷⁸

145. Given the tension between compliance with the Corporate Integrity Agreement and the desire to sell more OxyContin, Purdue needed help.

146. Ethan Rasiel, a former McKinsey consultant, has described the typical way McKinsey begins working with a client: “An organization has a problem that they cannot solve with their internal resources. That's the most classic way that McKinsey is brought in.”⁷⁹

147. Such was the case with Purdue. Because it did not have the requisite expertise to address the problems posed by the Corporate Integrity Agreement internally, Purdue expanded on its already-existing relationship with McKinsey to devise a sales and marketing strategy to increase opioid sales despite the Corporate Integrity Agreement and growing concern about the “concentration of risk” that Purdue's business of selling opioids posed to its owners.

⁷⁶ David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9, 2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

⁷⁷ PPLPC012000226606, Purdue Pharma Executive Committee Meeting Notes and Actions, May 20, 2009, Pg. 2.

⁷⁸ *Id.*

⁷⁹ *How McKinsey Became One of the Most Powerful Companies in the World*, CNBC, June 6, 2019 available at: https://www.youtube.com/watch?v=BBmmMj_mII

1 148. McKinsey's task was to thread the needle: to increase OxyContin sales despite the
2 strictures imposed by the five-year Corporate Integrity Agreement. This McKinsey did,
3 turbocharging⁸⁰ the sales of a drug it knew fully well was addictive and deadly, while purporting
4 to respect to the Corporate Integrity Agreement.

5 149. In short, Purdue would pay money to McKinsey in exchange for McKinsey
6 enabling the company how to sell as much OxyContin as conceivably possible so that the
7 Sacklers could obtain cash to diversify their investment holdings away from Purdue, and keep
8 their money safe from the reach of court judgments, fines, and penalties they feared.

9 150. Consistent with their plan to dissociate themselves from the company, the Sacklers
10 appointed Mr. Stewart as the CEO of Purdue in 2007. The Sacklers viewed Stewart as someone
11 loyal to the family. He had previously worked for a division of Purdue in Canada. Stewart's job
12 was to assist the Sacklers with the divestiture or eventual orderly wind-down of Purdue. Stewart
13 was paid more than \$25 million for his services to Purdue from 2007 through 2013.

14 151. Purdue's Executive Committee discussed Stewart's concerns regarding the
15 constraints posed by the Corporate Integrity Agreement on May 20, 2009. Within weeks,
16 McKinsey was working with Purdue to devise and implement new marketing strategies for
17 OxyContin.

18 152. Stewart, as CEO, was in charge of the relationship with McKinsey. He controlled
19 workflow to and from McKinsey and required his personal approval for any work orders with
20 McKinsey.

21 153. In addition, Purdue's Vice President of Corporate Compliance, "responsible for
22 developing and implementing policies, procedures, and practices designed to ensure compliance
23 with the requirements set forth in the [Corporate Integrity Agreement]," reported directly to
24 Stewart.⁸¹

25
26
27
28 ⁸⁰ If the description is overbearing, note that it is McKinsey's own, as described below.

⁸¹ PDD1712900096.

154. Throughout their relationship, McKinsey routinely obtained information from, advised, communicated with, and ultimately worked for the Purdue board of directors, controlled by the Sackler family.

155. McKinsey would also work in granular detail with the Purdue sales and marketing staff, led during the relevant period by Russell Gasdia, Vice President of Sales and Marketing.

156. From as early as June 2009 and continuing at least through July 14, 2014, Purdue routinely relied upon McKinsey to orchestrate its sales and marketing strategy for OxyContin. The relationship was characterized by ongoing interactions between teams from McKinsey and Purdue regarding not only the *creation* of an OxyContin sales strategy, but also its *implementation*. McKinsey was a real presence at Purdue. “A team of McKinsey analysts went in-house, camping out in a conference room at Purdue headquarters.”⁸²

5. Purdue Relies on McKinsey.

157. Purdue hired McKinsey not only to give advice, but to devise and then implement a deceptive marketing strategy. For example, for one “major initiative” with Purdue, “McKinsey forecast[ed] a potential incremental increase in sales in the \$200-400mm range” over a three-year period, “[w]hen properly implemented.”⁸³

158. McKinsey is not cheap, either. Indeed, hiring McKinsey is an expensive proposition. A single junior consultant—typically a recent college or business school graduate—runs clients millions of dollars annually.⁸⁴ McKinsey is a highly selective employer and advertises that its employees join “for the opportunity to apply their talents to complex, important challenges.”⁸⁵ “Talent” is key to McKinsey’s model; clients pay for the best and brightest.

159. A client does not choose to pay McKinsey unless it expects to receive benefits it could not have obtained within its own organization. McKinsey offers solutions to clients facing

⁸² Patrick Radden Keefe, *Empire of Pain* 302 (2021). In September, McKinsey named Mr. Keefe’s history of the Sackler family and Purdue and the opioid crisis to its 2021 shortlist for “Business Book of the Year.” See <https://www.mckinsey.com/about-us/new-at-mckinsey-blog/for-your-reading-list-the-2021-business-book-of-the-year-shortlist>

⁸³ PPLPC012000257444

⁸⁴ Ian MacDougal, *How McKinsey is Making \$100 Million (and Counting) Advising on the Government’s Bumbling Coronavirus Response*, ProPublica (July 15, 2020), <https://www.propublica.org/article/how-mckinsey-is-making-100-million-and-counting-advising-on-the-governments-bumbling-coronavirus-response>.

⁸⁵ <https://www.mckinsey.com/about-us/overview>

1 challenges they feel they cannot adequately address on their own. This model has been a stunning
 2 success for McKinsey. In 2008, McKinsey's annual revenue was \$6 billion. Today, the firm earn
 3 more than \$10 billion in revenue each year.⁸⁶

4 160. Clients pay these exorbitant rates for a reason: McKinsey's plans and partnership
 5 work. Even critics of the consulting industry recognize the unique efficacy of McKinsey's work.
 6 JPMorgan Chase CEO Jamie Dimon once derided consultants as "substituted management" and
 7 stated that "consultants can become a disease for corporations." Dimon made one exception to
 8 this rule: McKinsey.⁸⁷ Given unique levels of trust, respect, and access by major corporations
 9 across the United States and the world, McKinsey has unmatched power to affect how those
 10 corporations behave.

11 161. When Purdue entered into a "Master Consulting Agreement" with McKinsey in
 12 2004, Purdue explicitly recognized McKinsey "has a fine reputation as well as excellent
 13 experience and relationships in our industry," which Purdue was counting on to boost its opioids
 14 business.⁸⁸

15 162. Purdue explicitly recognized that McKinsey stepped in to help Purdue "protect
 16 [its] sales and continue to *grow our business*."⁸⁹

17 163. Furthermore, that the Sacklers, as board members of Purdue, relied on McKinsey
 18 in their conduct of Purdue affairs is an admitted fact. In a public filing in the recent Purdue
 19 bankruptcy proceedings, the one side of the Sackler family conceded that they did so: "McKinsey
 20 is widely recognized as 'a leading management consulting firm' and the Former Directors were
 21 statutorily entitled to rely on such expertise."⁹⁰

22 **6. McKinsey Delivers.**

23 164. Purdue, as a monoline manufacturer of opioids, relied on McKinsey in practically
 24 all aspects of its business.

25 _____
 26 ⁸⁶ Forbes, *McKinsey & Company* (retrieved September 9, 2021), <https://www.forbes.com/companies/mckinsey-company/?sh=1201a12624c1>.

27 ⁸⁷ Duff McDonald, *Behind the singular mystique of McKinsey & Co.* The Guest Blog. CNBC. Sept 25, 2013.
 Available at: <https://www.cnbc.com/2013/09/25/behind-the-singular-mystique-of-mckinsey-co.html>

28 ⁸⁸ PPLPC012000069192

⁸⁹ *Id.* (emphasis added).

⁹⁰ *In re: Purdue Pharma, L.P.*, No. 19-23649, Doc. 3441-1, at ¶ 328 (Aug. 5, 2021).

a. Courting the Regulators: “We All Feel Responsible.”

165. One critical aspect of Purdue’s operations, given its status as a producer of controlled substances, was regulatory compliance. McKinsey guided Purdue through practically all of its interactions with regulators whose efforts to protect the public might pose threats to Purdue’s business.

166. McKinsey advised Purdue on how to approach the FDA in light of its criminal conviction and retain business in light of the reputational damage to the company and to OxyContin after the admissions in its guilty plea.

167. In 2008, Purdue submitted a New Drug Application for a reformulation of OxyContin, ostensibly to make it more difficult to abuse by extracting the active ingredient from it or otherwise defeating the time-release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively promote as safer than and less prone to abuse than it was.

168. Having advised Purdue on the design of tests of reformulated OxyContin as part of Purdue’s FDA submission, McKinsey knew that reformulated OxyContin could still be abused. Purdue nonetheless touted its introduction of reformulated OxyContin and another ADF opioid as evidence of its good corporate citizenship and commitment to protecting the public. McKinsey worked with the Sacklers to prepare for Purdue’s meetings with the FDA.

169. On January 20, 2009, McKinsey partner Maria Gordian wrote to partners Rob Rosiello and Martin Elling to update them on these ongoing efforts with Purdue:

We had a very good FDA rehearsal yesterday *with several family members present*. The team did an outstanding job on the study. [P]reparing the client and executing the mock meeting. We are off to DC today for the actually (sic) FDA meeting tomorrow.⁹¹

170. Gordian’s email to Rosiello and Elling forwarded encouraging words from Richard Sackler. He wrote to his daughter, Marianna:

I am writing to tell you how impressed I was by the preparation for the FDA meeting. Both the method and the process as well as the content was excellent and a major

⁹¹ The Ad Hoc Group of Non-Consenting States’ Statement in Support of the Official Committee of Unsecured Creditors’ Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex D, Pg. 25 (emphasis added).

1 departure from efforts like this in the past. Please share with the team my views and
2 best wishes for a successful interchange with the FDA.⁹²

3 Marianna forwarded the well-wishes to Gordian and the team at McKinsey.

4 171. In September 2009, Purdue made a presentation to the FDA advisory committee
5 considering its application for its reformulated OxyContin and stated that the new formulation
6 would deter abuse. According to metadata, the PowerPoint presentation was prepared by
7 McKinsey.

8 172. The FDA approved the reformulation of OxyContin in April 2010.⁹³

9 173. Having successfully navigated the approval process with McKinsey's chaperoning,
10 Purdue then proceeded to market the ADF version of OxyContin as a solution to opioid abuse and
11 as a reason that doctors could continue to safely prescribe their opioids.

12 174. In 2020, two FDA advisory committees evaluating the impact of the reformulated
13 OxyContin concluded that reformulated OxyContin did not, in fact, substantially reduce abuse.

14 175. At the same time as it worked to rehabilitate Purdue's image with the FDA,
15 McKinsey, in parallel, advised Purdue on how to limit FDA regulations aimed at mitigating the
16 risks of opioid use. In 2008, shortly after Purdue's criminal plea, the FDA requested Purdue
17 submit a proposed "Risk Evaluation and Mitigation Strategy" ("REMS") for OxyContin.
18 McKinsey provided Purdue with drafts of the submission.⁹⁴ Indeed, McKinsey was crucial in
19 devising Purdue's response to the FDA's request for a REMS proposal from Purdue. Gordian
20 informed Rosiello and Elling on October 23, 2008 that John Stewart, Purdue's CEO, "is aware of
21 the critical role we are playing in pulling REMs together and is very appreciative." In the same
22 email, she noted that "the family" was focused "on the response to the non-approval letter" from
23 the FDA.⁹⁵

24 176. In 2009, the FDA expanded its scope to a class-wide extended release/long-acting
25 REMS program.

26 ⁹² *Id.*

27 ⁹³ See <https://www.fda.gov/media/126835/download>

28 ⁹⁴ PDD8901578031

⁹⁵ The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex C, Pg. 22.

177. Seeking to avoid a requirement that prescribers undergo mandatory training on OxyContin's risks or management or obtain certification before prescribing OxyContin, which would limit the numbers of available prescribers, Purdue turned to McKinsey. McKinsey found the cost to Purdue of a system to verify completion of prescriber education before prescriptions could be filled would be \$50 million—an estimate Purdue used to oppose efforts for more rigorous risk management strategies.⁹⁶

178. Armed with McKinsey's analysis, Purdue's strategy on REMS was effective. The REMS program avoided verification and enrollment provisions that would harm Purdue's profits.

179. Meanwhile, based on McKinsey's work on extended release opioid REMS, McKinsey was aware of warnings and adverse events included within the OxyContin medication guide and communications plans, including risks of overdose and adverse events including dizziness and lethargy.

180. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee meeting.

181. McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated OxyContin: Question & Answer Book" in September 2009, with questions including "Why should we trust you?" In response, McKinsey recommended Purdue say "We acknowledge mistakes made in the past[;]" "We have x, y and z measures in place that did not exist before[;]" and "[a]t all levels, Purdue's focus is on maintaining the highest ethical standards and meeting the needs of patients[.]"⁹⁹

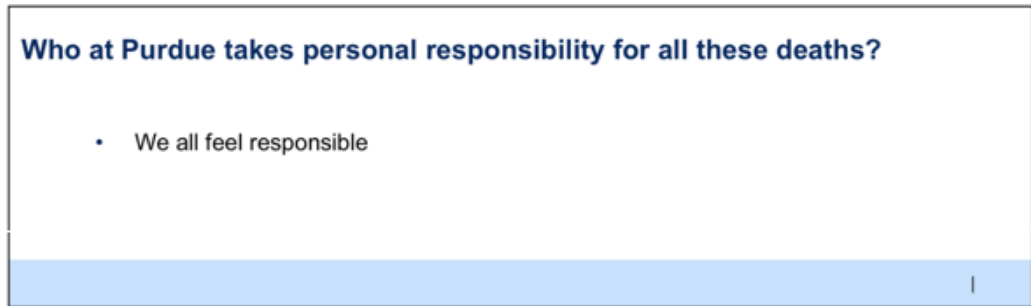
⁹⁶ PDD8901530124

⁹⁷ PPLPC019000622253

⁹⁸ PDD8901645845

⁹⁹ MCK-MAAG-0152135

182. Sometimes, McKinsey's work was as obfuscating as it was self-revealing. To the question of "Who at Purdue takes personal responsibility for all these deaths?[,]" McKinsey offered the following response:¹⁰⁰



MCK-MAAG-0152135 |

b. The Granularity of Growth

183. To this end, McKinsey prides itself on certain managerial techniques it professes to have detailed knowledge of and expertise in deploying. These techniques are generally applicable to problems encountered by many businesses; they are conceptual frameworks that McKinsey deploys when tasked with solving a problem for a client.

184. After Purdue's first guilty plea, the Sacklers desired dramatic, short-term growth of Purdue's opioid sales so as to increase the company's attractiveness as an acquisition target or borrower while allowing the Sacklers to take money out of the company. One service McKinsey offers to its clients is to tell them how to grow.

185. In order to identify growth opportunities for a client, McKinsey espouses a "granular" approach to identifying which subsets of the client's existing business are the sources of growth, and exploiting them for all they are worth. In August 2008, McKinsey directors Patrick Viguerie and Sven Smit, together with Mehrdad Baghai, published a treatise on the matter: *The Granularity of Growth: How to Identify the Sources of Growth and Drive Enduring*

¹⁰⁰ The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex F, Pg. 39.

1 *Company Performance* (Wiley, April 2008). “The key is to focus on granularity, to breakdown
2 big-picture strategy into its smallest relevant components.”¹⁰¹

3 186. Previously, in an article in *McKinsey Quarterly* (coincidentally published the same
4 month that Purdue pled guilty), the authors explained:

5 Our research on revenue growth of large companies suggests that executives should
6 “de-average” their view of markets and develop a granular perspective on trends,
7 future growth rates, and market structures. Insights into subindustries, segments,
8 categories, and micromarkets are the building blocks of portfolio choice. Companies
9 will find this approach to growth indispensable in making the right decisions about
10 where to compete.¹⁰²

11 187. Additionally, McKinsey encouraged a granular assessment of the geography of
12 corporate growth. “The story gets more precise as we disaggregate the company’s performance
13 on the three growth drivers in 12 product categories for five geographic regions.”¹⁰³

14 188. One can imagine this strategy applied to a seller of, say, cartons of milk. If
15 McKinsey were to perform an analysis of the milk seller’s sales and marketing and discover that
16 the profit margin on milk cartons sold to university cafeterias in dairy-producing states is much
17 greater than the margin on cartons sold at convenience stores in the southwest, and further that the
18 milk seller has previously devoted equal amounts of time and resources selling to both university
19 cafeterias and convenience stores, then McKinsey would likely advise the client to deploy
20 additional resources towards selling milk to university cafeterias in dairy-producing states.
21 McKinsey’s “granular” approach to the milk seller’s business channels has identified a way to
22 increase higher margin sales, leading to newfound growth and profitability for the client.

23 189. Rather than milk, McKinsey deployed this strategy on OxyContin, a controlled
24 substance, after its manufacturer pled guilty to misrepresenting the addictive and deadly
25 properties of the drug.

26 ¹⁰¹ *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, available at:

27 <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth>

28 ¹⁰² Mehrdad Baghai et. al., *The granularity of growth*, McKinsey Quarterly, May 2007, available at:

<https://www.mckinsey.com/featured-insights/employment-and-growth/the-granularity-of-growth>

¹⁰³ *Id.*

c. “Identifying Granular Growth Opportunities for OxyContin”

190. McKinsey’s granular analysis of Purdue’s OxyContin sales efforts led to the implementation of a number of strategies to sell more pills.

191. By January 2010, McKinsey informed Purdue, in accordance with the lessons of McKinsey’s granular growth analysis, that Purdue could generate “\$200-400mm” in additional annual sales of OxyContin by implementing McKinsey’s strategies.¹⁰⁴

192. In November 2010, a McKinsey report instructed sales reps to maximize profits by “emphasizing [the] broad range of doses”—which meant pushing the doses that were highest and most profitable.¹⁰⁵

193. In 2012, John Stewart assigned McKinsey to “understand the significance of each of the major factors affecting OxyContin’s sales.”¹⁰⁶

194. This McKinsey did in excruciatingly granular detail, analyzing each sales channel for Purdue’s opioids to identify weaknesses, opportunities, and to suggest courses of action to improve performance. Many core themes of McKinsey’s work would be crystallized in a series of presentations and updates made to the Sackler family and to Purdue’s board of directors in the summer of 2013 entitled “Identifying Granular Growth Opportunities for OxyContin.”

i. Marketing – Countering Emotional Messages

195. From the outset of McKinsey’s known work for Purdue, the work was grim. In June 2009, McKinsey teamed with Purdue’s then-Chief Medical Officer (and current CEO) Craig Landau and his staff to discuss how best to “counter emotional messages from mothers with teenagers that overdosed in [sic] OxyContin.”

196. Months later, McKinsey advised Purdue to market OxyContin based on the false and misleading notion that the drug can provide “freedom” and “peace of mind” for its users, give patients “the best possible chance to live a full and active life,” and concomitantly reduce stress and isolation.¹⁰⁷

¹⁰⁴ PPLPC012000257443; PPLPC012000257446

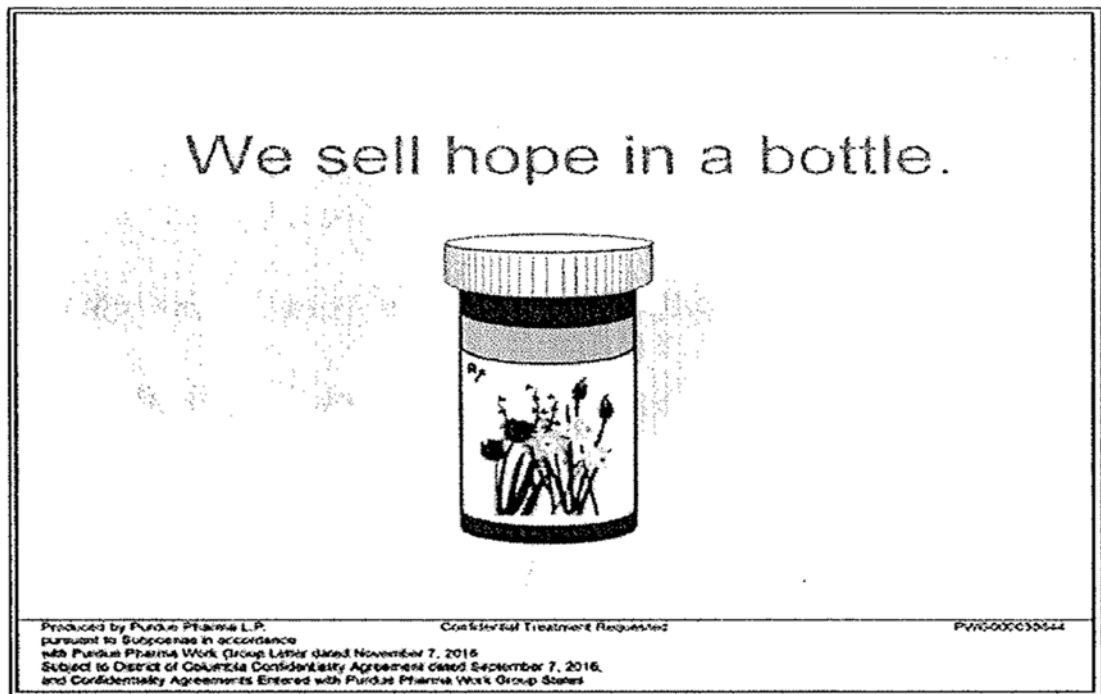
¹⁰⁵ PPLPC018000346294

¹⁰⁶ PPLPC020000587064

¹⁰⁷ PPLPC023000239858

197. These marketing claims were tailored to avoid any pitfalls that the Corporate Integrity Agreement might hold. While false and misleading, these claims regarding “freedom” and “peace of mind” of OxyContin users were narrowly tailored in order to avoid representations regarding “the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue’s products,” as specified in Section III.B.2.c of the Corporate Integrity Agreement.¹⁰⁸

198. Purdue’s marketing materials from that time period are illustrative of the approach.¹⁰⁹



199. Likewise, McKinsey informed Purdue that by highlighting the ability to “tailor the dose” and treat a “broad range of appropriate patients,” the prescriber-takeaway would be that “physicians can help their patients function better and lead a fuller and more active life,” even though this conclusion was not to be explicitly addressed.¹¹⁰

Take-away (not addressed)

... so physicians can help their patients function better and lead a fuller and more active life

¹⁰⁸ PDD1712900096

¹⁰⁹ *Tennessee v. Purdue Pharma L.P.*, Case No. 1-173-18 (Compl. May 15, 2018) ¶ 24.

¹¹⁰ PPLPC019000329253

200. Claims that OxyContin improved function and quality of life were not supported by substantial evidence and, in addition, failed to take into account risks of addiction. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.¹¹¹ A Centers for Disease Control and Prevention guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."¹¹² According to the CDC director, "for the vast majority of patients, the known, serious, and too-often- fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."¹¹³

201. In addition to crafting carefully-tailored quality of life assurances designed to avoid the pitfalls of the Corporate Integrity Agreement, McKinsey invented other misleading marketing efforts for Purdue.

202. For instance, McKinsey urged Purdue to capitalize on OxyContin's extended-release characteristics in another way: marketing OxyContin's twelve-hour dosing as though users only need to take OxyContin twice a day, thus requiring fewer pills. OxyContin in fact was well known to wear off after eight to ten hours in many patients, however. What McKinsey called "convenient," would later be called "a [d]escription of Hell."

203. This misleading assurance of twelve-hour relief is especially pernicious, as end-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a

¹¹¹ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); ALLERGAN_MDL_00387583; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). ALLERGAN_CA_00161496. The FDA's warning letters were available to McKinsey on the FDA website.

¹¹² CDC Guideline at 2, 18.

¹¹³ Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

1 craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the
 2 Washington University School of Medicine in St. Louis, called OxyContin's twelve-hour dosing
 3 "the perfect recipe for addiction."¹¹⁴ Many patients will exacerbate this cycle by taking their next
 4 dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall
 5 amount of opioids they are taking. Promotion of twelve-hour dosing, without disclosing its
 6 limitations, is misleading because it implies that the pain relief supplied by each dose lasts twelve
 7 hours.

8 204. In addition to designing misleading marketing messages, McKinsey even
 9 suggested encouraging a new channel through which those messages could be delivered to
 10 prescribers. McKinsey encouraged the tactic of "patient pushback," wherein McKinsey and
 11 Purdue would foment patients to directly lobby their doctors for OxyContin even when those
 12 physicians expressed reservations regarding the administration of Purdue's opioids.

13 205. The idea was that McKinsey and Purdue could spread their own message through
 14 pain patients who would be perceived as more credible sources suggesting a need for controlled
 15 or extended release opioid—even though the team devising this strategy would have known that
 16 extended release opioids did not substantially control pain or thwart addiction better than lower-
 17 dose, immediate release opioids.¹¹⁵

18 206. McKinsey also coached Purdue on building "trust" (which from its vantage point,
 19 McKinsey knew was misplaced) in Purdue following its criminal conviction.

20 **ii. Targeting – Selling More OxyContin to Existing High**
 21 **Prescribers**

22 207. Perhaps the key insight McKinsey provided was, using its granular approach, to
 23 identify historically large prescribers and target ever more sales and marketing resources on them,
 24 without any regard for, and indeed conscious disregard of, patient safety. Physician targeting
 25 proved effective. McKinsey advised Purdue that visiting high-prescribing doctors many times per
 26 year increased sales. This relentless drive to increase sales and create greater availability of

27 ¹¹⁴ Harriet Ryan, "'You Want a Description of Hell?' OxyContin's 12-Hour Problem," Los Angeles Times, May 5,
 28 2016, available at <http://www.latimes.com/projects/oxycontin-part1/>.

¹¹⁵ PDD8901645845

1 opioids was made with no notable concern about the parallel increase in opioid-related deaths,
2 abuse, and misuse.

3 208. On January 20, 2010, Purdue's board was informed of the ongoing work
4 McKinsey was performing concerning a new "physician segmentation" initiative whereby
5 McKinsey would analyze the opioid prescribing patterns of individual physicians to identify those
6 that had historically been the highest prescribers.¹¹⁶ McKinsey then worked with Purdue's sales
7 and marketing staff to specifically target those prescribers with a marketing blitz to encourage
8 even further prescribing.

9 209. Purdue trained its sales force in tactics to market to these high prescribers based on
10 McKinsey's insights and designed in conjunction with McKinsey.

11 210. Many of the historically highest prescribers of OxyContin—those same individuals
12 that McKinsey urged Purdue to target for ever more prescriptions—had prescribed Purdue's
13 OxyContin *before* the 2007 guilty plea and had already been subjected to Purdue's
14 misrepresentations regarding OxyContin that were the subject of that guilty plea.

15 211. McKinsey identified these physicians—those that had already been influenced by
16 Purdue's misrepresentations and were thus already high prescribers—as optimal targets for a
17 massive marketing push to sell more OxyContin.

18 212. McKinsey worked assiduously with Purdue over many years to continually refine
19 this approach and required ever-more granular data for its analysis. More than three years after
20 the initial introduction of the physician segmentation initiative, McKinsey requested, and Purdue
21 provided, "prescriber-level milligram dosing data" so that McKinsey could further analyze the
22 individual amounts of OxyContin prescribed by individual physicians.

23 213. At the same time it requested this "prescriber-level milligram dosing data" from
24 Purdue, McKinsey urged the Sacklers to strictly manage the target lists of each sales
25 representative to assure that the maximum amount of each sales representative's time was spent
26 with the most attractive customers.

27
28 _____
¹¹⁶ PPLPC012000257446

1 214. On July 23, 2013, Purdue’s board discussed concerns about “the decline in higher
2 strengths” of Purdue’s opioids as well as an observed decline in “tablets per Rx.” In order to
3 assure that the threat to OxyContin sales growth be addressed, McKinsey was assigned “to
4 actively monitor the number and size of opioid prescriptions written by individual doctors.”¹¹⁷

5 215. In unveiling Project Turbocharge to Purdue and the Sacklers, McKinsey stated that
6 the most prolific OxyContin prescribers wrote “25 times as many OxyContin scripts” as less
7 prolific prescribers and urged Purdue and the Sacklers to “make a clear go-no go decision to
8 ‘Turbocharge the Sales Engine’” by devoting substantial capital toward McKinsey’s plan.¹¹⁸

9 216. McKinsey also stated that increased numbers of visits by sales representatives to
10 these prolific prescribers would increase the number of opioid prescriptions that they would write.
11 This singular focus on increasing prescriptions was not coupled with colorable concern for the
12 patient population.

13 217. By November 2013, McKinsey had obtained the physician-level data they had
14 previously requested and continued to study ways to sell additional OxyContin prescriptions by
15 refining and targeting the sales pitch to them. The Purdue board was kept apprised of McKinsey’s
16 progress.

17 218. Not only did McKinsey identify which doctors prescribed the most of Purdue’s
18 opioids, McKinsey also recommended segmenting prescribers into “types” and tailoring messages
19 and tactics to the different prescriber profiles. For prescribers dubbed “Early Adopting Experts”
20 and “Proactive Teachers,” defined by a willingness to use extended release opioids, including in
21 opioid naïve patients (patients who were not already using opioids), McKinsey urged
22 emphasizing that its seven tablet strengths provide flexibility to “tailor the dose” to customer
23 needs.¹¹⁹ Upon information and belief, this message aimed to encourage prescribers to initiate and
24 maintain patients on OxyContin long-term by reminding them they could increase the dose as
25 patients became tolerant with long-term use (rather than discontinue use when the drug lost its
26 effectiveness).

27 ¹¹⁷ PPLP004307354

28 ¹¹⁸ PPLP004409890

¹¹⁹ MCK-MDL2296-0126522

219. In its October 26, 2009 presentation, “OxyContin – driving growth through stronger brand loyalty,”¹²⁰ McKinsey proposed tactics to turnaround declining sales, “[e]nhance loyalty to OxyContin among loyalist prescribers,” “[c]onvert[ing] ‘fence sitters’ into more loyal OxyContin prescribers,” and “[p]rotect OxyContin’s market share[.]”¹²¹ In other words, McKinsey proposed increasing sales by pushing both willing and reluctant physicians to prescribe more OxyContin.

220. McKinsey also recommended a strategy to target those prescribers who did not regularly prescribe OxyContin—so-called “Resigned Followers and ER Delayers” —encouraging them to “increase step-up” to extended release opioids. These were physicians with “low comfort with extended release opioids.” McKinsey encouraged Purdue to emphasize to them the “range of appropriate patients.” In other words, McKinsey’s strategy recommended that Purdue encourage prescribers to use OxyContin earlier in a patient’s treatment for a wider range of patients and for longer periods of time.

iii. Titration – Selling Higher Doses of OxyContin

221. McKinsey understood that the higher the dosage strength for any individual OxyContin prescription, the greater the profitability for Purdue. Of course, higher dosage strength, particularly for longer periods of use, also contributes to opioid dependency, addiction and abuse. Nonetheless, McKinsey advised Purdue to focus on selling higher strength dosages of OxyContin.

222. Consistent with its granular growth analysis, as early as October 26, 2009, McKinsey advised the Sacklers and the Purdue board that Purdue should train its sales representatives to “emphasiz[e] the broad range of doses,” which would have the intended effect of increasing the sales of the highest (and most profitable) doses of OxyContin.¹²²

223. McKinsey’s work on increasing individual prescription dose strength continued throughout the time period McKinsey worked with Purdue. The Sacklers were informed on July 23, 2013 that Purdue had identified weakness in prescribing rates among the higher doses of

¹²⁰ *Id.*

¹²¹ *Id.* at 2.

¹²² PPLPC018000346294

1 OxyContin and reassured the Sacklers that “McKinsey would analyze the data down to the level
2 of individual physicians” in order to study ways to maximize the sales of the highest-dose
3 OxyContin pills.

4 224. Purdue implemented McKinsey’s suggestions through adopting the marketing
5 slogan to “Individualize the Dose” and by 2013 encouraged its sales representatives to “practice
6 verbalizing the titration message” when selling Purdue’s opioids to prescribers.¹²³

7 225. McKinsey would have known, however, that higher doses of opioids carry greater
8 risk. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine
9 equivalent dose (“MED”) per day) as part of long-term opioid therapy are three to nine times
10 more likely to suffer overdose from opioid-related causes than those on low doses. As compared
11 to available alternative pain remedies, scholars have suggested that tolerance to the respiratory
12 depressive effects of opioids develops at a slower rate than tolerance to opioids’ analgesic effects.
13 The Centers for Disease Control and Prevention also recognize that higher doses of opioids tend
14 to increase overdose risks relative to any potential patient benefit.¹²⁴

15 226. Claims that opioids could be taken in ever-increasing strengths to obtain pain
16 relief, without disclosing that higher doses increased the risk of addiction and overdose, are
17 deceptive and misleading. They were particularly important to promotional efforts, however,
18 because patients on opioids for more than a brief period develop tolerance, requiring increasingly
19 high doses to achieve pain relief. Marketers needed to generate a comfort level among doctors to
20 ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

21 227. Purdue adopted McKinsey’s [REDACTED] proposal.¹²⁵ [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

26 ¹²³ PPLP003450924

27 ¹²⁴ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States,
2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

28 ¹²⁵ PPLPC023000251226 ([REDACTED]); see also

PPLPC012000243668 ([REDACTED]); PPLPC012000245087 ([REDACTED])

[REDACTED]; PPLPC012000246009 ([REDACTED]); PPLPC021000265092 ([REDACTED])

1 [REDACTED]
2 [REDACTED]¹²⁶

3 228. The titration messaging worked. Nationwide, based on an analysis by the *Los*
4 *Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on
5 doses greater than sixty milligrams per day, which converts to the ninety MED that the CDC
6 guideline urges prescribers to “avoid” or “carefully justify.”¹²⁷

7 **iv. Covered Persons – Sales Quotas and Incentive Compensation**

8 229. McKinsey urged the use of quotas and bonus payments to motivate Purdue’s sales
9 force to sell as many OxyContin prescriptions as possible. As McKinsey described it, “[r]evision
10 to incentive comp could better align reps to Purdue’s economics.”¹²⁸

11 230. Notably, this behavior was prohibited by the 2007 Corporate Integrity Agreement,
12 which required Purdue to implement written policies regarding “compensation (including salaries
13 and bonuses) for [sales representatives] engaged in promoting and selling Purdue’s products that
14 are designed to ensure that financial incentives *do not inappropriately motivate such individuals*
15 *to engage in the improper promotion or sales of Purdue’s products.*”¹²⁹

16 231. By 2010, Purdue had implemented a four-year plan, consistent with McKinsey’s
17 strategy, to dramatically increase the quota of required annual sales visits by Purdue sales
18 representatives to prescribers. The quota was 545,000 visits in 2010, 712,000 visits in 2011,
19 752,000 in 2012, and 744,000 visits in 2013.

20 232. On August 15, 2013, as part of their “Identifying Granular Growth Opportunities
21 for OxyContin” presentation, McKinsey urged the Sacklers to “establish a revenue growth goal
22 (e.g., \$150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO
23 and Board.”¹³⁰

24 233. In its “Identifying Granular Growth Opportunities for OxyContin” presentation to
25 the Purdue board in July 2013, McKinsey nonetheless urged Purdue, in addition to increasing the

26 _____
¹²⁶ PKY183123435

27 ¹²⁷ CDC Guideline at 16.

28 ¹²⁸ PPLPC012000441016

¹²⁹ PDD1712900096 (emphasis added).

¹³⁰ PPLP004409890

focus of the sales force on the top prescribers, to increase the overall quotas for sales visits for individual sales representatives from 1,400 to 1,700 annually.

234. In 2013, McKinsey identified one way that Purdue could squeeze more productivity out of its sales force: by slashing *one third* of the time that Purdue devoted to training its sales force (from 17.5 days per year to 11.5 days):

One possible way to attain benchmark ~1500 calls per year is to decrease training days by ~6 days and increase calls per day by 5%

One possible route to benchmark

Current call activity		Potential new allocation	
Number of "on territory" days per year		Number of "on territory" days per year	
Item	Days ¹	Item	Days ¹
Number of working days	260	Number of working days	260
Holidays	-11.3	Holidays	-11.3
Vacation and other time off	-27.2	Vacation and other time off	-27.2
Trainings and meetings	-17.5	Trainings and meetings	-11.5
Other company-related time off of field	-4.3	Other company-related time off of field	-4.3
Total days	199.7	Total days	205.7
Avg calls per day	x 7	Avg calls per day	x 7.35
Total calls per year	1398	Total calls per year	1512

¹ Purdue 2012 Actual data was used for this analysis

SOURCE: Purdue; team analysis

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235. By eliminating one third of the amount of time sales representatives were required to be in training, McKinsey projected that Purdue could squeeze an additional 5% of physical calls per day out of its newly less-trained sales force.

236. Additionally, McKinsey developed and advised Purdue on a new incentive compensation structure for the sales representatives, who were Covered Persons pursuant to the Corporate Integrity Agreement. McKinsey knew that, combined with the strictures of sales quotas and less training for the sales force, bonus/incentive compensation to the sales representatives based on the number of OxyContin prescriptions the representative produced could be a powerful driver of incremental OxyContin sales, without regard for patient safety.

1 **7. Transformation: Purdue and McKinsey Adopt and Implement**
 2 **McKinsey's Strategies.**

3 237. As early as September 11, 2009, McKinsey determined and told Purdue that it
 4 could generate \$200 million to \$400 million in additional annual sales of OxyContin by
 5 implementing McKinsey's strategy based on the opportunities its granular growth analysis had
 6 identified. McKinsey reiterated its assurances regarding the hundreds of millions of dollars of
 7 additional OxyContin sales on January 20, 2010.

8 238. Purdue accepted and, with McKinsey's ongoing assistance, implemented
 9 McKinsey's strategies for selling and marketing OxyContin.

10 239. For instance, in January 2010, Purdue was training its sales and marketing force on
 11 the new sales tactics based on a "physician segmentation" initiative that McKinsey urged. The
 12 strategy developed as a result of McKinsey's granular analysis of OxyContin sales channels. The
 13 initiative sought to identify the most prolific OxyContin prescribers and then devote significant
 14 resources towards convincing those high prescribers to continue to prescribe ever more
 15 OxyContin, in higher doses, for longer times, to ever more patients.

16 240. On January 20, 2010, the Purdue board was informed of the progress in
 17 implementing McKinsey's "physician segmentation" initiative.

18 241. This transformative collaboration would continue over the course of the
 19 relationship between Purdue and McKinsey.

20 242. During the time that McKinsey was working with Purdue, Purdue deliberately
 21 minimized the importance of the Corporate Integrity Agreement. In 2008, Carol Panara joined the
 22 Purdue sales force from rival Novartis. She would stay with the company until 2013, during
 23 which time McKinsey was responsible for increasing OxyContin sales at Purdue, and culminating
 24 with the implementation of McKinsey's "Project Turbocharge," beginning September 2013.

25 243. Ms. Panara stated that the 2007 guilty plea was deliberately minimized by the
 26 company in presentations to its sales staff: "They said, 'We were sued, they accused us of mis-
 27 marketing, but that wasn't really the case. In order to settle it and get it behind us we paid a fine.'
 28

1 You had the impression they were portraying it as a bit of a witch hunt.”¹³¹ (Purdue and its
2 executives paid \$634.5 million in fines.)

3 244. Consistent with McKinsey’s mandate, McKinsey devised methods for sales staff to
4 sell OxyContin to doctors while at the same time maintaining technical compliance with the
5 Corporate Integrity Agreement. Ms. Panara stated that, though she was told she could not flatly
6 claim that OxyContin was better or safer than other opioids, “she was trained to talk about
7 product in ways that implied that it was safer.” She might tout OxyContin’s twelve-hour
8 formulation to a prescriber. “You could say that with a shorter-acting medication that wears off
9 after six hours, there was a greater chance the patient was going to jump their dosing schedule
10 and take an extra one a little earlier. We couldn’t say [it was safer], but I remember we were told
11 that doctors are smart people, they’re not stupid, they’ll understand, they can read between the
12 lines.”¹³²

13 8. Project Turbocharge

14 245. The Corporate Integrity Agreement expired in January 2013. With this restriction
15 lifted, McKinsey devised additional marketing and sales strategies for Purdue to further increase
16 OxyContin sales.

17 246. On May 14, 2013, McKinsey entered into a “Statement of Services to the Master
18 Consulting Agreement” (the “2013 Agreement”) with Purdue to “conduct a rapid assessment of
19 the underlying drivers of current OxyContin performance, identify key opportunities to increase
20 near-term OxyContin revenue and develop plans to capture priority opportunities.” [REDACTED]

21 [REDACTED]
22 [REDACTED]¹³³

23 247. The 2013 Agreement stated, “We have a long history of partnership with Purdue,
24 and we would make best efforts to leverage our understanding of your business – both in terms of
25 content and culture.” It was signed by then-principal Arnab Ghatak, who would “lead the team
26

27 ¹³¹ David Crow, *How Purdue’s ‘one-two’ punch fuelled the market for opioids*, Financial Times, September 9, 2018,
28 available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

¹³² *Id.*

¹³³ PPLPC030000770531

1 with senior leadership from Rob Rosiello and Martin Elling.” Elling was a leader of McKinsey’s
2 PMP group.¹³⁴

3 248. McKinsey was tasked with “Identifying Granular Growth Opportunities for
4 OxyContin,” conducting an “assessment of the underlying drivers of current OxyContin
5 performance,” identifying “key opportunities to drive near-term OxyContin performance,” and
6 developing “plans to capture priority opportunities.”¹³⁵

7 249. For purposes of the project, McKinsey would need “[f]ull access to work done to
8 date and key data.”¹³⁶ And, [REDACTED]

9 [REDACTED]¹³⁷

10 250. Staff told the Sacklers that McKinsey would study how to get doctors to prescribe
11 more OxyContin,¹³⁸ how to use incentive compensation to push reps to generate more
12 prescriptions, how to use “patient pushback” to get doctors to prescribe more opioids, and how to
13 keep patients on opioids longer.¹³⁹

14 251. The 2013 Agreement would lead to Project Turbocharge, McKinsey’s successful
15 bid to transform Purdue’s sales and marketing efforts for OxyContin now that Purdue was no
16 longer bound by the Corporate Integrity Agreement.

17 252. In the summer of 2013, McKinsey made multiple recommendations to Purdue’s
18 board to increase OxyContin revenue, and urged the Sackler family to “make a clear go-no-go
19 decision to ‘Turbocharge the Sales Engine.’”

20 253. Purdue, like McKinsey, recognized that the initiative was no small thing. An
21 internal Purdue email states that [REDACTED]

22 [REDACTED]¹⁴⁰

23 254. The Sacklers were impressed. On August 15, 2013, Richard Sackler emailed
24 Mortimer D.A. Sackler, “[T]he discoveries of McKinsey are astonishing.”

25 _____
¹³⁴ *Id.*

26 ¹³⁵ PPLPC030000770531 / MCK-MAAG-0024283

27 ¹³⁶ *Id.*

28 ¹³⁷ PPLPC012000431809

¹³⁸ PPLPC012000431262

¹³⁹ *Id.*; PPLPC012000431266

¹⁴⁰ PPLPC012000437344

1 255. Eight days later, on August 23, 2013, McKinsey partners met with the Sackler
2 family—not the Purdue board of directors—to pitch Project Turbocharge. Dr. Arnab Ghatak, one
3 of the McKinsey partners leading the Purdue account, recounted the meeting to fellow McKinsey
4 partner Martin Elling in an email exchange: “[T]he room was filled only with family, including
5 the elder statesman Dr. Raymond [Sackler] We went through exhibit by exhibit for about 2
6 hrs They were extremely supportive of the findings and our recommendations . . . and
7 wanted to strongly endorse getting going on our recommendations.”¹⁴¹

8 256. Elling, a co-leader of the Purdue account, remarked in the same email
9 correspondence that McKinsey’s “findings were crystal clear to” the Sacklers, and that the
10 Sacklers “gave a ringing endorsement of ‘moving forward fast.’”¹⁴²

11 257. As a result of the Sackler family endorsement of McKinsey’s proposals, the
12 following month Purdue implemented Project Turbocharge based on McKinsey’s
13 recommendations. In adopting “Project Turbocharge,” Purdue acknowledged the improper
14 connotations of the name, and re-christened the initiative the decidedly more anodyne “E2E:
15 Evolve to Excellence.”¹⁴³

16 258. Evolve to Excellence (“E2E”) was the theme of Purdue’s 2014 National Sales
17 Meeting.

18 259. CEO John Stewart also told sales staff that board member Paolo Costa was a
19 “champion for our moving forward with a comprehensive ‘turbocharge’ process,” referring to
20 McKinsey’s plan.

21 260. After Purdue adopted McKinsey’s recommendations, McKinsey continued to work
22 with Purdue sales and marketing staff reporting to Russell Gasdia during Purdue’s
23 implementation of McKinsey’s recommendations.

24
25
26 ¹⁴¹ MCK-MDL2996-0403095

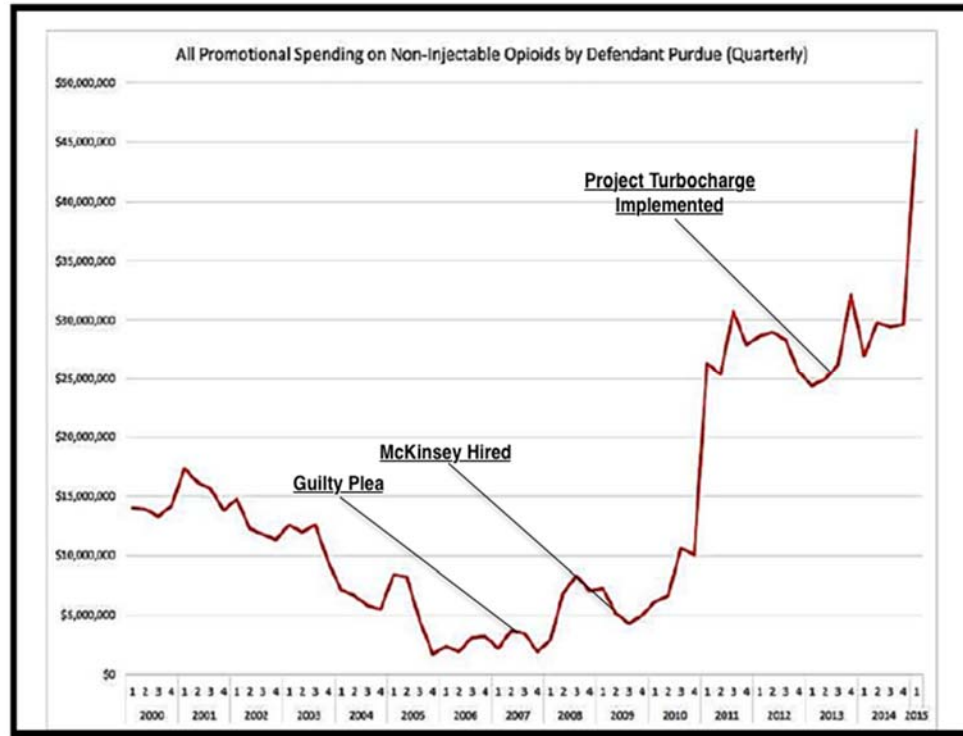
27 ¹⁴² *Id.*

28 ¹⁴³ Regarding the name change, CEO John Stewart wrote to McKinsey partners Rob Rosiello and Arnab Ghatak on August 15, 2013: “Paolo Costa was especially engaged in the discussion and he (among others) will be a champion for our moving forward with a comprehensive ‘turbocharge’ process – *though we do need to find a better and more permanently appropriate name.*” PPLPC012000436626 (emphasis added).

261. In fact, the entire E2E initiative was overseen by McKinsey and some Purdue executives, who together comprised the E2E Executive Oversight Team and Project Management Office.

262. At the same time, the Sacklers were kept informed of the implementation of McKinsey's OxyContin strategy. According to a September 13, 2013 board agenda, the board discussed with the Sacklers the ongoing implementation of McKinsey's sales tactics.

263. Evolve to Excellence called for a *doubling* of Purdue's sales budget. Under McKinsey's prior tutelage, Purdue's promotional spending had already skyrocketed. McKinsey's ongoing influence on Purdue's operations after the 2007 guilty plea is stark:



264. At the time of McKinsey's first known work for Purdue, Purdue spent approximately \$5 million per quarter on sales and marketing. By the time McKinsey's Project Turbocharge was implemented, total quarterly sales and marketing spending at Purdue exceeded \$45 million, an increase of 800%.

265. Project Turbocharge continued despite the arrival of a new CEO at Purdue. On January 17, 2014, new CEO Mark Timney received reports from McKinsey emphasizing that, in

1 order to increase profits, Purdue must again increase the number of sales visits to “high-value”
 2 prescribers, i.e., those that prescribe the most OxyContin.¹⁴⁴

3 266. Purdue and McKinsey worked together to implement “Turbocharging the Sales
 4 Engine.” [REDACTED]

5 [REDACTED]
 6 [REDACTED]¹⁴⁵

7 267. McKinsey and Purdue also worked together on an “implementation plan” for E2E,
 8 with McKinsey taking on the role of “executive oversight” of projects including the creation of
 9 target lists, internal dashboards to track progress, and changes to Purdue’s incentive
 10 compensation plan consistent with E2E.¹⁴⁶

11 **a. Targeting High Subscribers**

12 268. Project Turbocharge called for revising the existing process for targeting high-
 13 prescribing physicians, with a shift from targeting solely on the basis of prescription deciles to
 14 considering additional factors. Based on its analysis, McKinsey told Purdue that “[t]here is
 15 significant opportunity to slow the decline of OxyContin by calling on more high-value
 16 physicians” and that “[t]he revenue upside from sales re-targeting and adherence could be up to
 17 \$250 million.”

18
 19
 20 ¹⁴⁴ In fact, recent deposition testimony suggests McKinsey may have been responsible for the fact that Timney was
 21 given the CEO job at Purdue in the first place. On October 30, 2020, Timney provided the following testimony
 (emphasis added):

22 Q: Are you familiar with McKinsey & Company?

23 A: I decline to answer on the ground that I may not be compelled to be a witness against
 myself in any proceeding.

24 Q: Did individuals at McKinsey assist you in getting hired as the CEO of Purdue?

A: I decline to answer on the ground that I may not be compelled to be a witness against
 myself in any proceeding.

In fact, McKinsey appears to have played a substantial role in the succession of several Purdue CEO’s.
 25 Martin Elling, in his 2018 annual self-assessment, provided the following example of “how I deliver
 impact:” “Actively managing CEO/CXO transitions: ... from Michael Friedman to John Stewart (2007) to
 26 Mark Timney (2014) to Craig Landau (2017) at Purdue.” MCK-MDL2996-0357931. “I drove our
 introduction of Purdue in 2004 and then, with Rob Rosiello, built it into a substantial and sustaining client...
 27 We have served across four CEOs and are now helping the new leadership team adapt to a world of
 headwinds for their core product OxyContin,” he added. MCK-MDL2996-0357931.

28 ¹⁴⁵ PPLPC021000615265

¹⁴⁶ MCK-MDL2996-0180338, at 0180340

1 269. The core objective of McKinsey’s initiative was to ensure that Purdue was
2 “making calls on the highest potential customers with the right frequency to maximize prescribing
3 potential.”

4 270. McKinsey determined and advised Purdue that the top half of prescribing
5 physicians “write on average 25 times more scripts per prescriber” than the lower half. McKinsey
6 advised that Purdue would see a greater return on its sales investment by focusing on these
7 targets, including on prescribers with alarming prescribing patterns that raised red flags they were
8 writing “prescriptions” for non-medical use. McKinsey’s plan aimed at boosting sales of
9 OxyContin by targeting the highest volume opioid prescribers, without addressing whether the
10 expanded sales would be for an illicit market.

11 271. McKinsey found that Purdue did not “focus on the highest potential docs,”
12 measured both by the number of prescriptions and reimbursement considerations.¹⁴⁷ One
13 McKinsey analyst urged McKinsey to recommend Purdue target “[l]iterally, at least all”
14 prescribers in the top 20% of prescribers, “minus another few percent who are no sees[.]”¹⁴⁸
15 McKinsey team lead Arnab Ghatak replied that “they probably have 20% no see[], but i’d also
16 assume there are not many high writers that are no see.”¹⁴⁹ (“No see” prescribers are prescribers
17 who do not accept visits from pharmaceutical sales representatives. Thus, McKinsey recognized
18 that most of the highest volume prescribers, or “high writers” of prescriptions, were willing to
19 entertain sales visits from sales representatives.)

20 272. “To put this in perspective,” McKinsey stated,

21 the average prescriber in decile 5-10 [the top half of prescribers by volume] writes
22 25 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the
23 majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers.
24 Including the secondary calls, 57% of the primary detail equivalents (PDEs) were
25 made to decile 0-4 prescribers. Best practice in the industry is over 80% of effort on
26 higher value prescribers.”

27 _____
147 MCK-MDL2996-0364024


28 148 MCK-MDL2996-0364267

149 *Id.*

McKinsey concluded: “Given that there are 14,000 uncalled physicians in deciles 5-10, there is significant opportunity to shift calls to higher potential prescribers.”¹⁵⁰

273. McKinsey pointed to a “true physician example” in Wareham, Massachusetts, who wrote 167 more OxyContin prescriptions after Purdue sales reps visited him.¹⁵¹

True physician example



Specialty : Anesthesiology

Location : Wareham, Massachusetts

Market Decile : 8

	12 months ending March 2012	12 months ending March 2013
Calls made on physician	0 P1 1 P2	18 P1 1 P2
OxyContin scripts written during 2 nd half of year	177	344

Graphic from McKinsey presentation recommending targeting high prescribers

274. To slow or reverse the decline in OxyContin sales, McKinsey recommended a shift to “value deciles,” which purported to weigh prescribers according to factors including overall opioid prescriptions, including the number of branded versus generic prescriptions; prescriber rules in place limiting sales calls; managed care access; and the number of the prescribers new to brand prescriptions, including new opioid patients and switches from other opioid products.¹⁵² The cumulative effect of the value rankings was to shift detailer emphasis onto the highest-volume prescribers. Further, McKinsey’s analysis found that the highest-volume prescribers were themselves most influenced by detail visits.

275. Purdue moved quickly to do as McKinsey advised. All sales representatives received a memo on December 23, 2013, identifying how to select “SuperCore” prescribers, or the top ten targets,¹⁵³ in their territory according to the E2E high prescribing principles and

¹⁵⁰ MCK-MDL2996-0187168 / PPLP004409892

¹⁵¹ PPLPC012000437356

¹⁵² PPLPC022000646874

¹⁵³ MCK-MDL2996-0316833

1 required that each SuperCore prescriber be visited at least twice a month.¹⁵⁴ [REDACTED]

2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]¹⁵⁵ As part of these changes, McKinsey's plan involved *more* minimum sales calls
 5 overall.¹⁵⁶

6 276. [REDACTED]
 7 [REDACTED]

8 [REDACTED] who later plead guilty to criminal charges related to an opioid drug ring. The
 9 prescriber also surrendered his license to practice after an Ohio Medical Board investigation
 10 revealed that he prescribed excessive and dangerous combinations of opioids and muscle relaxers
 11 and that he prescribed opioids to a patients who complained of headaches and others who showed
 12 signs of addiction.¹⁵⁷ The same prescriber received at least sixty visits from Purdue from mid-
 13 2013 through 2016.¹⁵⁸

14 277. [REDACTED]
 15 [REDACTED]
 16 [REDACTED]

17 The doctor, who worked at a family practice, was
 18 charged with involuntary manslaughter, Medicaid fraud, drug trafficking, grand theft, and other
 19 offenses.

20 278. [REDACTED]
 21 [REDACTED]

22 [REDACTED]¹⁵⁹ In 2018, the Drug Enforcement Administration issued an Order to Show Cause and
 23 Immediate Suspension Order to Dr. Khan-Jaffrey over concerns that her DEA registration
 24 "constituted an imminent danger to the public health and safety," finding she prescribed opioids
 25 without a legitimate medical purpose and disregarded urine screens indicating abuse and

¹⁵⁴ PURCHI-000005915

¹⁵⁵ PPLPC022000686986

¹⁵⁶ MCK-MDL2996-0187168

¹⁵⁷ https://www.cnhinews.com/article_91ffac58-1b32-11e8-b264-6b34793bf5c3.html

¹⁵⁸ Public information about visits at which a payment was made is available for this time period through "Open Payments."

¹⁵⁹ PPLPC014000257127

diversion.¹⁶⁰ Dr. Khan-Jaffrey's DEA registration was fully revoked on July 28, 2020.¹⁶¹ Dr. Louis Spagnoletti, of Marlton, New Jersey, [REDACTED] [REDACTED]¹⁶² lost his state license to prescribe controlled substances in 2018.¹⁶³ Similarly, Dr. Vivienne Matalon, a Decile 10 prescriber from Cherry Hill, New Jersey, [REDACTED] [REDACTED]¹⁶⁴ went on to lose her license in 2018 as well, for allegedly receiving kickbacks to prescribe the fentanyl drug Subsys to three patients, including one that died.¹⁶⁵

279. Another prescriber, Dr. Damon Cary of Wilmington, Delaware, [REDACTED] [REDACTED]¹⁶⁶ received an emergency suspension order in 2019 after prescribing controlled substances, including opioids, to undercover officers without performing any medical examinations.¹⁶⁷ Dr. Eva Dickinson, of Harrington, Delaware, [REDACTED] [REDACTED]¹⁶⁸ was arrested on marijuana charges in 2016 and had her license suspended in 2017 for sharing drugs, including opioids, with her patients.¹⁶⁹

280. Dr. Michael Cozzi of Fort Wayne, Indiana, [REDACTED] [REDACTED], had his medical license suspended in 2016, where he had prescribed more controlled substances than any other Indiana prescriber, with over two million doses of oxycodone, seeing ninety to 100 patients a day.¹⁷⁰ Dr. Jamie Gurrero, [REDACTED] [REDACTED]¹⁷¹ was sentenced to 100 months in prison in

¹⁶⁰ <https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order>

¹⁶¹ *Id.*

¹⁶² PPLPC014000257127

¹⁶³ <https://patch.com/new-jersey/moorestown/state-suspends-doctor-accused-illegally-prescribing-opioids>

¹⁶⁴ PPLPC014000257127

¹⁶⁵ <https://nj.gov/oag/newsreleases18/pr20180504d.html>

¹⁶⁶ PPLPC014000257130

¹⁶⁷ <https://www.delawareonline.com/story/news/health/2019/08/05/doctor-prescribed-opioids-undercover-cops-failed-follow-protocol/1920386001/>

¹⁶⁸ PPLPC014000257130

¹⁶⁹ <https://www.delawareonline.com/story/news/health/2017/01/19/doctors-license-suspended-delaware-maryland/96779080/>

¹⁷⁰ <https://www.wane.com/news/fort-wayne-pain-doctors-medical-license-suspended/> (He later died in a tractor accident, <https://www.journalgazette.net/news/local/police-fire/20180816/tractor-accident-kills-pain-doctor>)

¹⁷¹ PPLPC014000257130

2016 after pleading guilty to unlawful distribution or dispensing of controlled substances, health care fraud, conspiracy, and money laundering.¹⁷²

281. [REDACTED]

[REDACTED] Misrepresentations to these prescribers were especially insidious because they were aimed at general practitioners who lack the time and expertise to closely manage higher-risk patients on opioids.

282. McKinsey also urged, consistent with continually refining its granular approach, that sales representatives devote two-thirds of their time to selling OxyContin and one-third of their time selling Butrans, another Purdue opioid product. Previously, the split had been fifty-fifty.

b. Circumventing Safeguards Against Abuse and Diversion

283. Project Turbocharge also involved a granular analysis of Purdue's individual sales channels. In its August 8, 2013 report to the Purdue board, McKinsey also attributed the decline in OxyContin sales to safeguards to limit suspicious opioid sales. McKinsey informed Purdue that "[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk." "There are reports of wholesalers stopping shipments entirely to an increasing number of pharmacies," "[m]any wholesalers are also imposing hard quantity limits on orders based on prior purchase levels," and "[p]harmacy chains are implementing guidelines for which patients can fill opioid prescriptions[.]"¹⁷³

284. For instance, McKinsey recommended that Purdue circumvent pharmacies entirely with a mail order program because enforcement by federal regulators was decreasing OxyContin dispensing through Walgreens. McKinsey informed the Sacklers that "[d]eep examination of Purdue's available pharmacy purchasing data shows that Walgreens has reduced its units by 18%." Further, "the Walgreens data also shows significant impact on higher OxyContin dosages."¹⁷⁴

¹⁷² <https://www.justice.gov/usao-wdky/pr/kentuckiana-anesthesiologist-sentenced-100-months-unlawful-distribution-controlled>

¹⁷³ MCK-MAAG-0024297

¹⁷⁴ *Id.*

285. In order to counter these perceived problems, McKinsey suggested that Purdue's owners lobby Walgreens specifically to increase sales and circumvent the safeguarding sales limits. It also suggested the establishment of a direct-mail specialty pharmacy so that Purdue could circumvent Walgreens and sell directly to Walgreens' customers. Finally, McKinsey suggested the use of opioid savings cards distributed in neighborhoods with Walgreens locations to encourage the use of Purdue's opioids despite Walgreens actions.

286. McKinsey's initiative also included ways to circumvent these safeguards. McKinsey recommended that the sales force distribute vouchers and "starter kits" for patients who faced co-pays for OxyContin prescriptions.¹⁷⁵ In particular, McKinsey recommended dispensing vouchers to outlets of a specific large national pharmacy chain where prescriptions and OxyContin inventories were down.¹⁷⁶ This chain, as part of its own settlement with the Drug Enforcement Administration, had removed pharmacist bonuses for dispensing opioids.¹⁷⁷

c. Incentivizing Opioid Sales

287. McKinsey's "turbocharging" plan also had other elements. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]¹⁷⁹

9. McKinsey's Efforts Triple OxyContin Sales

288. In 2013, despite significant headwinds, with marketing activities turbocharged, OxyContin sales peaked. The restrictions on Purdue's sales and marketing methods contained in the Corporate Integrity Agreement should have resulted in fewer overall OxyContin sales; the guilty plea identified a specific segment of existing OxyContin sales that were illegitimate and should thus cease. All else being equal, OxyContin sales should have decreased to account for the

¹⁷⁵ MCK-MDL2996-0290827.

¹⁷⁶ MCK-MDL2996-0041646.

¹⁷⁷ MCK-MDL2996-0104431; MCK-MDL2996-0041646.

¹⁷⁸ PPLPC012000437346.

¹⁷⁹ *Id.*

1 successful elimination of improper sales. In fact, OxyContin sales did decrease in the immediate
2 aftermath of the 2007 guilty plea.

3 289. And within five years, however, OxyContin sales would triple. McKinsey is
4 responsible for the strategy that accomplished this. It presented specific plans to Purdue, which
5 Purdue adopted and spent hundreds of millions of dollars implementing. The result: a final spasm
6 of OxyContin sales before the inevitable decline of the drug.¹⁸⁰

7 290. The Purdue McKinsey collaboration was a spectacular success. Between the 2008
8 and 2016, Purdue distributed in excess of \$4 billion to the Sackler family, with \$877 million
9 distributed in 2010 alone.

10 291. These distributions would not have been possible without the McKinsey's work
11 dramatically increasing OxyContin sales.

12 292. The Sacklers were aware of the value McKinsey provided: on December 2, 2013,
13 CEO John Stewart informed Kathe Sackler and Vice President of Sales and Marketing Russell
14 Gasdia Project Turbocharge "was already increasing prescriptions and revenue." Crucially, these
15 results were already being realized *before* the strategy was fully deployed as the theme of the
16 2014 National Sales Meeting. Stewart elaborated to Sackler that "trends are more positive than
17 was the case a few months back, and when the E2E Project (the changes arising out of the
18 McKinsey analysis) is fully implemented there will certainly be additional increases."¹⁸¹

19 293. Later that month, [REDACTED]

20 [REDACTED]¹⁸²

21 294. McKinsey's contributions to Purdue's growth after 2007 are remarkable.
22 OxyContin sales should have naturally declined; the Department of Justice identified OxyContin
23 sales that were illegitimate because of Purdue's conduct, and the Inspector General of the
24 Department of Health and Human Services entered into a Corporate Integrity Agreement whereby
25 Purdue was monitored to assure that those sales did not continue.

27 ¹⁸⁰ On February 10, 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin
sales force.

28 ¹⁸¹ PPLPC012000454422

¹⁸² PPLPC012000457292

1 295. In 2007, the year of Purdue's guilty plea, net sales of OxyContin totaled
2 approximately \$1 billion.¹⁸³

3 296. The guilty plea "did little to stem Purdue's blistering growth rate." In fact, by
4 2010, after McKinsey was advising Purdue on how to maximize sales, OxyContin sales exceeded
5 \$3 billion: a *tripling* of revenue from OxyContin sales.¹⁸⁴

6 297. Under McKinsey's guidance, OxyContin sales would reach their all-time peak in
7 2013, the year McKinsey proposed, and Purdue adopted, Project Turbocharge.¹⁸⁵ That OxyContin
8 sales peaked in 2013 is especially notable, given that *overall* opioid prescriptions had *already*
9 *peaked* three years earlier, in 2010.¹⁸⁶ McKinsey's efforts added a final boost to OxyContin sales
10 before the eventual unraveling, and Purdue's decision, in the end, to cease marketing the drug.

11 298. Project Turbocharge was a continuing success. [REDACTED]
12 [REDACTED]¹⁸⁷ and Chief Financial Officer Edward
13 Mahoney reported to the Purdue board that the effort "has resulted in significant improvement." [REDACTED]
14 [REDACTED]

15 [REDACTED]¹⁸⁸

16 299. McKinsey was paid handsomely: it received more than [REDACTED] for its work for
17 Purdue from 2008 to 2013 alone.¹⁸⁹ In pursuit of these profits, McKinsey continued to help Purdue
18 grow opioid sales even after Purdue reached a 2015 Assurance of Discontinuance with New York
19 arising out of an investigation concerning its Abuse and Diversion Detection program and media
20 coverage highlighted its lack of attention to diversion control. McKinsey's own work elsewhere
21 identified "reducing prescribing" as among the efforts to combat the opioid epidemic and also
22

23 ¹⁸³ See David Crow, *How Purdue's 'one-two' punch fueled the market for opioids*, Financial Times, September 9,
2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

24 ¹⁸⁴ *Id.*

25 ¹⁸⁵ Phil McCausland and Tracy Connor, *OxyContin maker Purdue to stop promoting opioids in light of epidemic*,
NBC News, February 10, 2018, available at: <https://www.nbcnews.com/storyline/america-heroin-epidemic/oxycontin-maker-purdue-stop-promoting-opioids-light-epidemic-n846726>

26 ¹⁸⁶ Gery P. Guy Jr., *at al.*, *Vital Signs: Changes in Opioid Prescribing Patterns in the United States, 2006-2015*,
Centers for Disease Control and Prevention, July 7, 2017, available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm>

27 ¹⁸⁷ PPLPC037000159028

28 ¹⁸⁸ PPLPC014000263961

¹⁸⁹ PPLPC029000547371

1 showed that opioid prescribers were frequently writing prescription for patients with known risks
2 of abuse. Still, McKinsey continued to work to help opioid manufacturers increase opioid sales,
3 including through Purdue's deceptive marketing campaign.

4 300. By 2014, according to Purdue, there were 5.4 million OxyContin prescriptions
5 written, 80% for twelve-hour dosing. Of those prescriptions, more than half were for doses
6 greater than sixty milligrams per day.

7 301. The Sackler family has withdrawn over \$10 billion from Purdue since 2008,
8 including \$1.7 billion in 2009 alone. These distributions were made possible by McKinsey's
9 services and came at the expense of a deepening national opioid crisis.

10 **E. McKinsey's Opioid-Related Work with Other Clients.**

11 302. Part of the unique value McKinsey provides is its deep knowledge of its clients'
12 competitors, often because it counts those same competitors as its clients. McKinsey generally
13 does not disclose to its clients its work for their competitors.

14 303. The opioid industry was no different. Indeed, McKinsey specifically worked to
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 **1. Endo**

19 304. While McKinsey was working for Purdue, McKinsey was also working for Endo
20 Pharmaceuticals. Arnab Ghatak was a principal McKinsey partner on both accounts at the same
21 time.¹⁹¹ There was additional overlap between the McKinsey teams staffed to Purdue and Endo,
22 including McKinsey partners Nicholas Mills and Laura Moran. After all, these particular
23 consultants had granular expertise in the specific subject-matter relevant to these opioid
24

25 ¹⁹⁰ MCK-MDL2996-0041741.

26 ¹⁹¹ Ghatak's familiarity with both Endo and Purdue is perhaps one reason why, on April 3, 2014, Ghatak was placed
27 in charge of analyzing a proposed *partnership* between Purdue and Endo to sell opioids. Laurant Moran described the
28 "partnership workstream" that McKinsey was then performing for Purdue to identify ways for Purdue to obtain near-
term growth. She stated that Purdue and McKinsey "agreed the partnerships workstream should include the top 3
potential partners (Valeant, Endo and Pfizer for now). And for each what assets each partner would bring and what
growth (most importantly) would the deal bring. Arnie [Ghatak] and Phil to work out Endo and Valeant, John G and
Raul to do Pfizer tomo." MCK-MDL2996-0421790.

1 manufacturers. That subject-matter expertise is a compelling reason why McKinsey is hired in the
 2 first place. McKinsey advised both Endo and Purdue how to maximize the sales of their branded
 3 opioid products—Belbuca (Buprenorphine), Butrans (Buprenorphine), Opana (Oxymorphone),
 4 and OxyContin (Oxycodone) —all at once.

5 **a. New Blues**

6 305. Like Purdue, Endo was historically a pharmaceutical manufacturer focused on the
 7 pain market. Like Purdue, Endo relied on opioid sales for a significant portion of its business. As
 8 a matter of fact, Endo’s history with opioids predates the Sacklers’ ownership of Purdue. In 1950,
 9 Endo’s predecessor, Intravenous Products of America, Inc., launched Percodan, an
 10 Oxycodone/Aspirin tablet. In 1971, Endo, then owned by E.I. du Pont de Nemours and Company
 11 (“DuPont”), launched Percocet, another oxycodone-based tablet.¹⁹²

12 306. In 1997, Endo separated from DuPont to become a standalone private company
 13 retaining Percodan and Percocet.¹⁹³ In 2000, as the result of an acquisition, the company became
 14 public.¹⁹⁴

15 307. In 2006, Endo launched its own branded oxymorphone products, Opana and
 16 Opana ER.¹⁹⁵ With the legacy assets of Percodan and Percocet, Endo’s business had always been
 17 focused on opioid sales. Oxymorphone is not a new opioid, and Opana was not Endo’s first
 18 oxymorphone product. It was first synthesized more than a century ago in Germany. Endo began
 19 selling it in the United States in 1959 under the name Numorphan.

20 308. Numorphan was referred to as “blues,” after the color of the 10mg pills. It
 21 delivered a more euphoric high than heroin, according to some. In 1974, the National Institute on
 22 Drug Abuse noted in its “Drugs and Addict Lifestyle” report that Numorphan was popular as an
 23 abused drug for its quick and sustained effect.¹⁹⁶ By 1979, Endo withdrew Numorphan from the
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26 ¹⁹² <https://www.endo.com/about-us/history#fragment-25>

27 ¹⁹³ <https://www.endo.com/about-us/history#fragment-24>

28 ¹⁹⁴ <https://www.endo.com/about-us/history#fragment-21>

¹⁹⁵ <https://www.endo.com/about-us/history#fragment-15>

¹⁹⁶ John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015),
 available at: <https://www.medpagetoday.com/psychiatry/addictions/51448>

1 market. Upon information and belief, [REDACTED]

2 [REDACTED]¹⁹⁷

3 309. The memory of the 1970s Numorphan addiction crises did not fade quickly. In
4 1989, the film *Drugstore Cowboy* featured Matt Dillon as an addict in the 1970s who robs drug
5 stores to obtain drugs to sell in order to finance his opioid dependency.¹⁹⁸ In one scene, an addict
6 asks Dillon's character if he has any "blues." Dillon's character explains that "blues" are
7 increasingly hard to find, and offers to sell morphine sulfate to an addict instead. The addict
8 explained that he much preferred the Numorphan, but settled for the morphine.¹⁹⁹

9 310. With the launch of Opana, Endo decided it was time for history to repeat itself.
10 After Opana's approval in 2006, Endo solidified its position as a pain specialist among
11 manufacturers. By 2012, opioid sales accounted for approximately \$403 million of Endo's \$3
12 billion in revenue, more than 10%. From 2010 to 2013, total Opana ER revenue alone exceeded
13 \$1.1 billion.

14 311. Opana and Numorphan were both oxymorphone. The brand name was the only
15 thing that changed. What Endo removed from the market in 1979 due to abuse concerns, it re-
16 introduced 27 years later. After 2006, Opana was on occasion referred to as "blue heaven," or,
17 more to the point, "new blues."²⁰⁰

18 312. In 2017, Endo would once again remove its branded oxymorphone product from
19 the market, and for the same reason. Endo's abuse-deterrent formulation of Opana was removed
20 at the request of the FDA due to acute concerns about its abuse potential.

21 313. In addition to its branded products, Endo, through subsidiaries Qualitest
22 Pharmaceuticals, Inc. and, after its acquisition in 2015, Par Pharmaceuticals, also manufactured
23 generic versions of oxycodone, oxymorphone, hydromorphone, and hydrocodone. Over the
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25 _____
26 ¹⁹⁷ EPI000443330 ([REDACTED])

27 [REDACTED]; ENDO-OPIOID-MDL-06246554 ([REDACTED])

28 [REDACTED]).

¹⁹⁸ See <https://www.imdb.com/title/tt0097240/>; <https://www.bionity.com/en/encyclopedia/Oxymorphone.html>

¹⁹⁹ Scene from *Drugstore Cowboy*, available at: https://www.youtube.com/watch?v=TksvZdrx9_A

²⁰⁰ https://www.deadiversion.usdoj.gov/drug_chem_info/oxymorphone.pdf

1 course of McKinsey's relationship with Endo, McKinsey would repeatedly advise Endo how to
2 maximize its generics business in addition to sales of Endo's branded opioids.

3 **b. Old Friends**

4 314. McKinsey's relationship with Endo began as early as in 2006, the same year as the
5 Opana launch.

6 315. McKinsey's earliest known work with Endo concerned the launch of Opana in
7 Europe, but its relationship with Endo would expand to encompass all aspects of Endo's business,
8 including corporate organization and resource allocation, the launch of a new branded
9 Buprenorphine product, and sales force optimization efforts for Endo's branded and generic
10 opioid products.

11 316. In 2007, McKinsey was shaping overall corporate strategy at Endo. In a
12 presentation to Endo's board of directors in May of that year [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED] 201

17 317. McKinsey's partnership with Endo would last more than a decade, and, like its
18 relationship with Purdue, is an exemplary example of the transformational relationship in action.

19 318. In some ways, the McKinsey's relationship with Endo was even more tightknit and
20 companionable than with Purdue. For instance, no one at Purdue previously worked for
21 McKinsey. In early 2013, Rajiv de Silva, previously a leader of McKinsey's PMP group, was
22 appointed CEO of Endo. At Endo, McKinsey was now advising an old friend, one of its previous
23 senior partners.²⁰²

24 319. As de Silva himself explained, "[REDACTED]

25 [REDACTED]

26 ²⁰¹ ENDO-OPIOID_MDL-02899510.

27 ²⁰² See "Rajiv De Silva Named President and CEO of Endo Health Solutions," Press Release dated February 25,
28 2013, *available at*: <https://investor.endo.com/news-releases/news-release-details/rajiv-de-silva-named-president-and-ceo-endo-health-solutions> ("Earlier in his career, he was a Principal at McKinsey & Company, where he served as a member of the partnership group that led the global Pharmaceuticals and Medical Products practice.")

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320. Under de Silva, Endo relied more heavily on McKinsey than ever before. McKinsey consultants interacted directly and often *exclusively* with de Silva. McKinsey was so close to the Endo CEO that it could intervene in direct reporting from one of de Silva's deputies.²⁰⁴ It is as if McKinsey had insinuated itself as a shadow layer of bureaucracy within Endo.

321. McKinsey maintained weekly performance review meetings with de Silva and senior Endo management. In these meetings, granular weekly sales data was reviewed for each of Endo's branded products, including Opana.²⁰⁵

322. McKinsey advised both Purdue and Endo contemporaneously for more than a decade. With each client, the goal was the same: to maximize opioid sales. The work McKinsey performed for each client was so similar that there was routinely confusion internally about whether a specific project or task to perform was for Endo or Purdue.²⁰⁶

323. Despite McKinsey's emphasis on confidentiality, the fact that McKinsey repeats its work from one client to the next is well-known to the client. Indeed, it is part of the justification in hiring McKinsey in the first place. McKinsey can tell you what everyone else is doing. [REDACTED]

²⁰³ ENDO-OPIOID-DEPMAT-000047877 at pg. 320:22 – 321:3.

²⁰⁴ See MCK-MDL2996-0405502 (Email from Ghatak to de Silva, stating that it “would be great for you to push Blaine and Bob [both Endo employees] on why there are no slides showing the metrics on field call attainment . . . there was an explicit agreement to track them. Setting the expectation that you want them included would really help”).

²⁰⁵ MCK-MDL2996-0062712.

²⁰⁶ In response to an internal email from Craig MacKenzie to other McKinsey consultants seeking “expert input on labels for abuse deterrent formulations” in conjunction with McKinsey’s work on the Belbuca launch (discussed *infra.*), McKinsey consultant Jeff Smith replied, “Craig – is this for Purdue or Endo? If for Endo, I am conflicted.” MCK-MDL2996-0383805.

²⁰⁷ ENDO-OPIOID-MDL-07619243.

c. Opana

324. McKinsey's earliest known work with Endo [REDACTED]

[REDACTED]. In a November 22, 2006 presentation²⁰⁸ entitled "[REDACTED]"

[REDACTED],” McKinsey advised [REDACTED]

”²⁰⁹

325. McKinsey noted, [REDACTED]

²¹⁰

326. McKinsey also [REDACTED]

”²¹¹

327. McKinsey advised [REDACTED]

²¹²

²⁰⁸ The McKinsey presentation was [REDACTED]

[REDACTED] ” ENDO-OPIOID_MDL-02936031. By 2007,

McKinsey had [REDACTED]

[REDACTED] ” ENDO-OPIOID_MDL-06078889. Endo acquired Penwest in 2010. “Endo Pharmaceuticals Agrees to Acquire Penwest Pharmaceuticals,” Fierce Biotech, August 10, 2010, *available at*: <https://www.fiercebitech.com/biotech/endo-pharmaceuticals-agrees-to-acquire-penwest-pharmaceuticals>

²⁰⁹ ENDO-OPIOID_MDL-02936031.

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.*

1 328. McKinsey [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]”²¹³

7 329. Within a few years of its introduction in the United States, abuse of the drug
 8 became widespread. Endo then sought to introduce a reformulated version of Opana that it could
 9 market as abuse-deterrent by introducing a tamper-resistant coating to the pill.

10 330. In December 2011, Endo obtained FDA approval for a new formulation of Opana
 11 ER with the coating that Endo claimed was crush-resistant. The following month, however, the
 12 FDA told Endo that it could not market Opana ER, even after the reformulation, as abuse-
 13 deterrent.

14 331. Endo “did not submit any new clinical safety or efficacy data” as part of its
 15 application, but rather relied entirely on the “bioequivalence” of the new and old formulations of
 16 Opana. Obtaining approval of reformulated Opana ER on this basis allowed Endo to rely on the
 17 safety and efficacy of the original version of the drug as the basis for approval of the reformulated
 18 version.²¹⁴ The FDA found that such promotional claims “may provide a false sense of security
 19 since the product may be chewed and ground for subsequent abuse.” In other words, Opana ER
 20 was still crushable. In December 2011, Endo admitted that “[i]t has not been established that this
 21 new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or
 22 addiction.”²¹⁵

23
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 25 ²¹³ *Id.*

26 ²¹⁴ Intervenor Impax Laboratories, Inc.’s (1) Cross-Motion to Dismiss; or, in the Alternative, (2) Opposition to
 27 Plaintiff’s Motion for a Preliminary Injunction, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et*
al. (“Impax Br.”), No. 1:12-cv-01936 Doc. 18 at 7 (D.D.C. Dec. 9, 2012); *see also* FDA Summary Review for
 28 Regulatory Action, NDA 201655 (Dec. 9, 2011) (stating that “[n]o new safety data were included in this submission”
 and “[n]o efficacy studies were submitted in this application.”).

²¹⁵ Endo Dec. 12, 2011 News Release; Ex. A to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug*
Administration, et al., No. 1:12-cv-01936 Doc. 18-2 (D.D.C. Dec. 9, 2012).

332. In 2013, an Endo training module directed key opinion leaders to instruct prescribers that OPANA ER with INTAC is the only oxymorphone designed to be “crush-resistant,” and advised the key opinion leaders to state during their speeches that “[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe OPANA ER with INTAC.”²¹⁶ The speakers were advised to stress that generic versions of Oxymorphone “are not designed to be crush-resistant.”

333. These abuse-deterrent attributes of the reformulation—the very characteristics McKinsey and Endo touted as a reason to prescribe Opana—were a sham. The reformulation was designed to prevent the pill from being crushed and snorted through the nose. It did not prevent intravenous use, however. The result was that many users already dependent of Opana began using needles to inject the drug for the first time. As an internal Endo email put it, [REDACTED]

[REDACTED],²¹⁷

334. Jeff, a veteran of the war in Iraq, explained the process. Jeff first became dependent on Percocet and Opana after returning from Iraq, where his back was injured when his Humvee rolled over in 2008. After being prescribed opioids for his back pain, Jeff became dependent, and began using Opana by snorting it. Endo then introduced the reformulated abuse-deterrent version of Opana in 2012. “[A]nd then they reformulated them,” he said, referring to the Opana pills. “And the only way you could really do them is inject them because if you actually swallow them, it – you – they really don’t do nothing.”²¹⁸

335. Jeff and his companion Joy showed the journalist how the drug was used. “You want to see how to cook it?” Jeff asked. He and Joy then proceeded to place a portion of an Opana pill on piece of aluminum and heat it with a lighter. “Right away, I can start to see this hard, white coating just kind of floating off the piece of the pill. It looks like plastic,” described the journalist witnessing the process.²¹⁹

²¹⁶ EPI000421543.

²¹⁷ END00010732.

²¹⁸ Kelly McEvers, “Opioid Epidemic Sparks HIV Outbreak in Tiny Indiana Town,” NPR, March 31, 2016, *available at*: <https://www.npr.org/2016/03/31/472577254/opioid-epidemic-sparks-hiv-outbreak-in-tiny-indiana-town>

²¹⁹ *Id.*

1 336. Joy explained how the abuse-deterrent coating, once melted, was discarded by
 2 using the filter of a cigarette: “Now you see the coating of – all that mess laying there still? . . .
 3 That’s what the filter’s for.”²²⁰ The journalist described what then took place:

4 And Joy puts that cigarette filter into the liquid, and they Joy, Jeff and another guy
 5 each take turns with their needles, sticking it into the filter and pulling the liquid
 6 through. Joy and Jeff turn their back to me while they inject. And then it just gets
 really, really quiet.

7 337. Joy couldn’t conceive of the position she was in. A nurse, she hurt her back at
 8 work and began taking prescription pain medication. She began taking the pills by mouth, and
 9 later began to snort them. Dependency began. But she told herself, “I’d never ever would use a
 10 needle, never. I’m never going to do that.”²²¹

11 338. After Opana’s reformulation, Joy began using it intravenously. “I started using the
 12 needle about – it was around the 6th of February,” she said. “I’m so ashamed . . . I pack so much
 13 shame, and I’m going to cry . . . I pack so much shame from it. I do.”²²²

14 339. Endo’s 2012 reformulation of Opana caused outbreaks of HIV in populations of
 15 intravenous Opana users. In Austin, Indiana, where Jeff and Joy resided, Opana was linked to an
 16 outbreak of at least 200 HIV cases in a town with a population of 4,500.²²³

17 340. Intravenous use of reformulated Opana has also been associated with outbreaks of
 18 Hepatitis C and Thrombotic Thrombocytopenic Purpura (“TTP”).²²⁴ The concerns even reached
 19 Wall Street, where an analyst asked Endo about a TPP outbreak in Tennessee associated with
 20 Opana ER. Endo assured the analyst that the outbreak was, like the outbreak in Indiana, in “a
 21 very, very distinct area of the country.”

22 341. Endo was well aware of these problems. [REDACTED]
 23 [REDACTED]
 24 [REDACTED]

26 ²²⁰ *Id.*

27 ²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

28 ²²⁴ “Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012,” *Morbidity and Mortality Weekly Report* (Jan. 11, 2013).

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342. In June of 2013, McKinsey

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343. McKinsey indicated

”228

344. In addition to being neither feasible nor safe/ethical, the study was beside the point. An insufflation study is meant to determine the abuse characteristics of a drug when used nasally—i.e., by snorting the drug.²²⁹ The relevant concern for Opana’s reformulated version was *injection*, not insufflation.

345. But the insufflation study worked for Purdue. Going forward, McKinsey suggested

”230

²²⁵ ENDO00260151.

²²⁶ EPI002107711.

²²⁷ *Id.*

²²⁸ *Id.* (emphasis added).

²²⁹ See General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products, FDA Center for Drug Evaluation and Research, November 2017, *available at*:

<https://www.fda.gov/files/drugs/published/General-Principles-for-Evaluating-the-Abuse-Deterrence-of-Generic-Solid-Oral-Opioid-Drug-Products-Guidance-for-Industry.pdf>

²³⁰ EPI002107711.

346. As the preceding paragraphs make clear, Endo and McKinsey were laser-focused on maximizing overall sales of Endo products, and decidedly *not* on concerns over their actual abuse potential or the appropriate *size* of the market for these products, given evident, longstanding, and ever-present concerns about their abuse. To the point, McKinsey regarded concerns about opioid abuse only as a means by which its clients could introduce *differentiated* products (i.e., those with purported abuse-deterrent or tamper-resistant features) to continually perpetuate overall opioids sales for their clients. In all instances, the parties desired for the size of that overall opioids market to grow in line with the introduction of “differentiated” products like a reformulated Opana.

347. Endo’s purported concern about deterring abuse of its drugs was laid bare as farce by a particularly striking decision: to continue to sell the old formulation of Opana despite touting the notion that the old formulation was purportedly dangerous in ways that the new formulation was not. Endo [REDACTED]

[REDACTED].²³¹

348. Endo not only continued to distribute original Opana for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers.²³² In fact, Endo also claimed in September 2012 to be “proud” that “almost all remaining inventory” of the original Opana ER had “been utilized.”²³³

349. In June 2013, an Endo employee informed the McKinsey consultants of a [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]²³⁴

²³¹ ENDO-OPIOID-MDL-02324795.

²³² Impax Br. at 1.

²³³ *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

²³⁴ ENDO-OR-CID-00400235 (emphasis added).

d. **Belbuca: Endo's Answer to Butrans**

350. Buprenorphine is another differentiated product. Opioid manufacturers began to introduce Buprenorphine products to the market after the introduction of OxyContin, Opana, and other branded opioids long-known to have abuse and dependency problems. Buprenorphine products were marketed as purportedly less dangerous than products such as OxyContin or Opana.

351. Of course, Endo and Purdue continued to assiduously market and sell OxyContin and Opana alongside their Buprenorphine products, and McKinsey worked with each at every step of the way, despite the implicit contradiction in marketing two products at the same time whose point of differentiation is one being *less addictive and dangerous* than the other.

352. For example, on August 13, 2015, McKinsey's Craig MacKenzie circulated a discussion document to Endo and McKinsey staff entitled "Belbuca value proposition," which laid out McKinsey's thoughts on how to differentiate Endo's buprenorphine product from other opioids in the marketplace.²³⁵ One point of differentiation McKinsey noted was that OxyContin was commonly abused, while Endo's Belbuca hopefully would not be:²³⁶

Product strengths

Comparative value propositions against Purdue products

		BELBUCA	OXYCONTIN [®] <small>(OXYCODONE HCl CONTROLLED-RELEASE TABLETS)</small>	Hysingla [®] ER
Safety	Abuse deterrence	Perceived due to inherent properties in formulation and molecule	Commonly abused; reformulated as "abuse deterrent" in 2010	Formulated with abuse deterrent properties
	Side effects/tolerability	Good tolerability after titration, low constipation	Average, can be associated with nausea, vomiting, & constipation	Lack of NSAID or tylenol decrease risk of adverse reaction

353. The cognitive dissonance was palpable. At the same time that MacKenzie sent his email differentiating Belbuca, and as described *supra*, McKinsey was *also* maximizing OxyContin sales for Purdue—the opioid it was describing to Endo as commonly abused.

²³⁵ MCK-MDL2996-0410742.

²³⁶ MCK-MDL2996-0006669, at 0006675.

1 354. [REDACTED]

3 [REDACTED] Butrans was Purdue's buprenorphine product.

4 355. Once Butrans was launched at Purdue, McKinsey worked with Endo to create
5 another branded Buprenorphine product to compete with Butrans. These product planning and
6 launch processes are long-term affairs. McKinsey worked with Endo on this project for *four years*
7 before Endo's Belbuca obtained FDA approval.

8 356. McKinsey remained in place at Endo to implement the launch of Endo's
9 Buprenorphine product. The strategic goal of Belbuca—the key to its commercial success—was
10 to convert short acting opioid (“SAO”) users to Belbuca. As McKinsey explained to CEO Rajiv
11 de Silva, “The fundamental question is whether Belbuca will take share from the short-acting
12 opioids.”²³⁷

13 357. Ultimately, Belbuca was not a large commercial success for Endo because it failed
14 to transition a sufficient number of short acting opioid users to the long-acting Belbuca. As the
15 drug underperformed, Endo felt ever more pressure to stimulate sales. John Harlow described one
16 meeting with de Silva on April 8, 2016: “We just got out of the review with Rajiv and clearly our
17 TRx trends are not good and are behind other recently launched pain products . . . the request
18 from Rajiv was to do anything possible that could be implemented ASAP to stimulate RXs.”²³⁸

19 358. By July 6, 2016, McKinsey and Endo were increasingly focused on converting
20 short-acting opioid users. [REDACTED]

21 [REDACTED]
22 [REDACTED].²³⁹ Notably, the goal was to increase *overall* buprenorphine
23 prescriptions, not only those of Belbuca. The discussion document identified an objective to
24 create “a new treatment paradigm for [Buprenorphine] and Belbuca at the transition between
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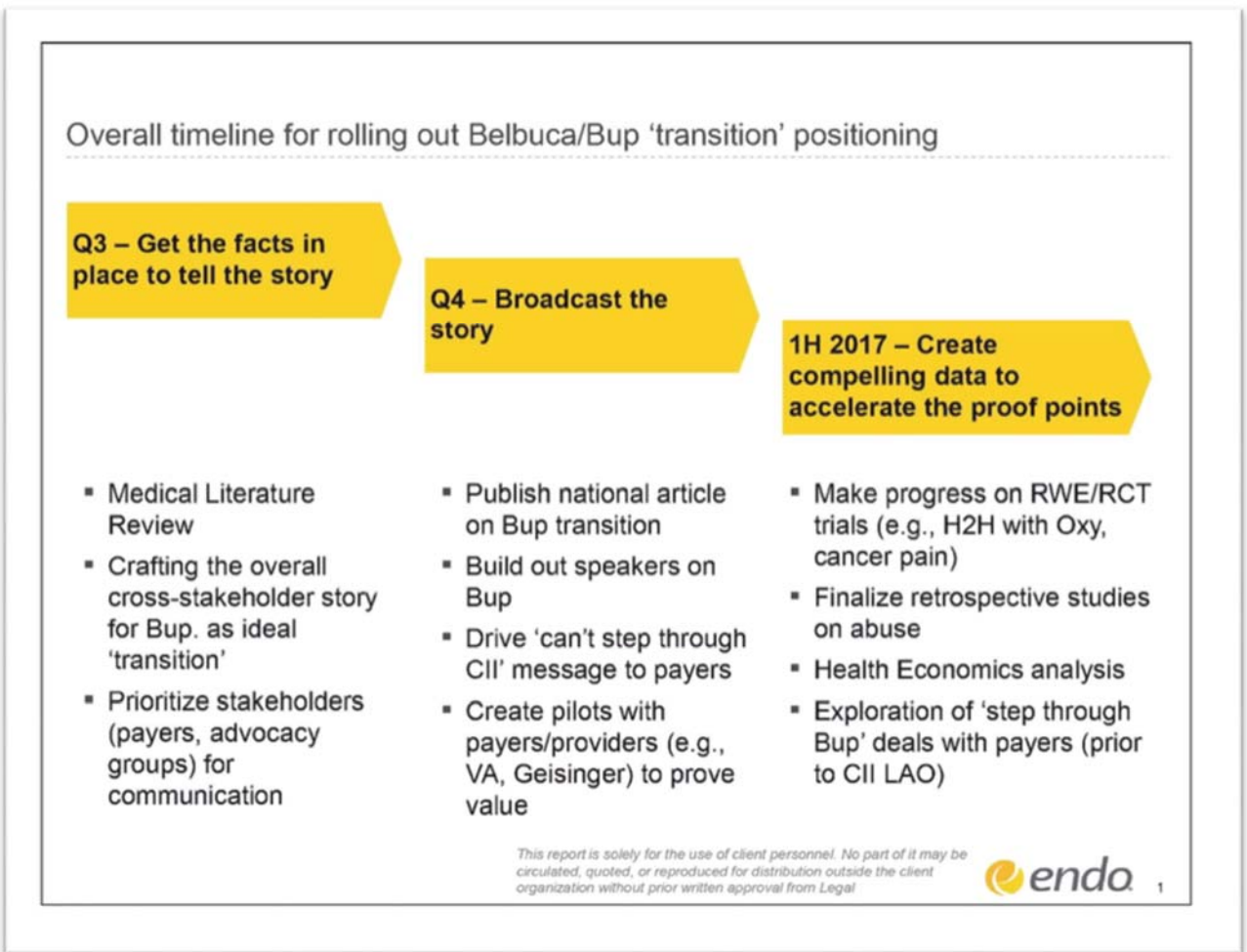
27 ²³⁷ MCK-MDL2996-0210158.

28 ²³⁸ MCK-MDL2996-0358973, at 0358975.

²³⁹ ENDO-OPIOID_MDL-07264539

SAO and LAO.”²⁴⁰ In order to do so, the discussion group needed to determine “what medical support we need to position Buprenorphine as the best transition from SAO to LAO.”²⁴¹

359. McKinsey provided a slide to Endo describing the way that narrative would first be *created* and then exploited for market positioning:²⁴²



360. McKinsey and Endo referred to this effort to revive Belbuca sales by promoting buprenorphine as a bridge to long-acting opioid use as a “moonshot.”²⁴³ One aspect of this “moonshot” would be that Belbuca (and Buprenorphine, generally) would convert short-acting opioid users to long-acting opioids users of products *other than Buprenorphine*. McKinsey and

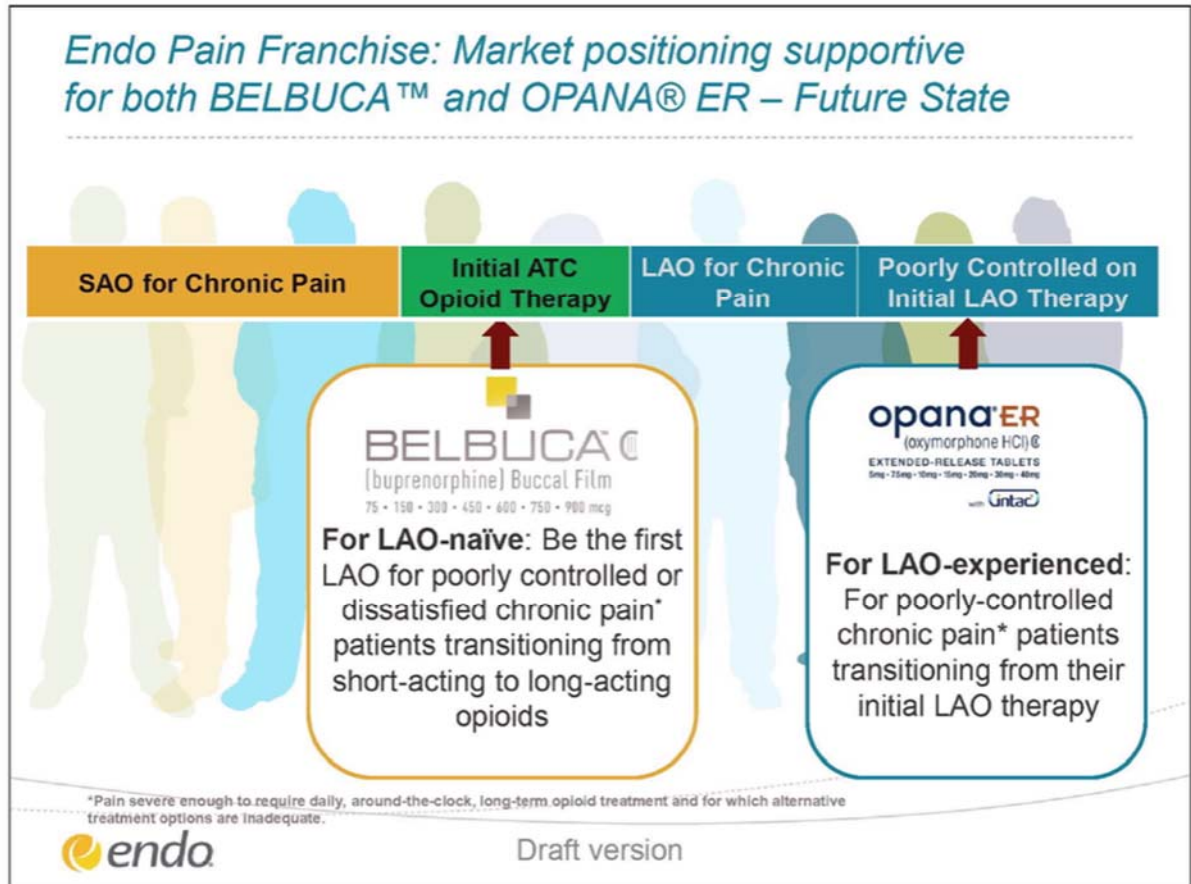
²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² MCK-MDL2996-0382731.

²⁴³ MCK-MDL2996-0382412.

Endo instead conceived of Belbuca as an “*Initial ATC Opioid Therapy*.” It was to be positioned as “the *first* LAO for poorly controlled or dissatisfied chronic pain patients transitioning from short-acting to long-acting opioids.” Patients could eventually transition from Belbuca to other long-acting opioids, like Opana.²⁴⁴



361. Thus, the overall marketing strategy McKinsey assisted Endo in designing and deploying for Belbuca was designed to transition ever more patients to long-acting opioids. Belbuca could find its market niche as a stepping stone as individuals proceed through the patient funnel from short acting opioid users to longer-term long-acting opioid users. The farther an individual proceeds through this funnel, the more the individual is worth.

362. McKinsey also knew that this same pathway that begins with opioid therapy after a serious injury also leads to opioid dependency and addiction. In 2011, McKinsey was working on “Project X,” which was the project to develop a buprenorphine product to compete with Butrans.

²⁴⁴ MCK-MDL2996-0404374, at 0404375.

(Belbuca, in other words, was the result of Project X.) McKinsey described the “opioid dependence treatment pathway” as follows:²⁴⁵

breakthrough thinking. collaboration. customer focus. accountability.

OPIOID DEPENDENCE TREATMENT PATHWAY

- Patient begins opioid therapy following serious injury/surgery
- Patient pain not controlled, dosages increase, patient seeks additional medication options
- Patient referred to pain specialist
- Patient shows up in ER, Clinic or seeks out addictionologist
- Addictionologist – Pain Specialist or Psychiatrist with additional license to prescribe Methadone, Subutex/Suboxone for opioid dependence
- Options
 - Methdone
 - Subutex initiation, followed by Suboxone treatment

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363. In the same presentation, McKinsey identified the key to a successful launch of a branded Buprenorphine product: “The challenge faced by Endo will not be to gain formulary approval, it will be to gain tier 2 status and *minimize restrictions on prescribing*.”²⁴⁶

e. Turbocharging the Sales Force with a Blitz

364. In 2015, a McKinsey team led by Arnab Ghatak proposed to Endo a sales transformation to invigorate Endo’s product sales, including its opioids. At the suggestion of Ghatak, McKinsey used the Purdue Pharma Project Turbocharge model from the previous year as a template for the Endo proposal.²⁴⁷ Even the PowerPoint presentations used to create the proposal to Endo were drafted off the Project Turbocharge slides. On June 28, 2015, Sherin Ijaz

²⁴⁵ MCK-MDL2996-0131500, at 0131512.

²⁴⁶ MCK-MDL2996-0131500, 0131525 (emphasis added).

²⁴⁷ MCK-MDL2996-0075895.

1 of McKinsey emailed Ghatak, Nicholas Mills, and Laura Moran to circulate a draft proposal for
 2 an “Endo sales force transformation” PowerPoint presentation. Ijaz explained, “Laura, I heavily
 3 leveraged what you send (sic) from Purdue as it was all applicable.”²⁴⁸ All three of the recipients
 4 of Ijaz’s email regarding the Endo proposal had been working on the Purdue account for years.

5 365. Endo [REDACTED]

8 [REDACTED] ²⁴⁹

9 366. Endo’s Vice President & General Manager of its Pain Business Unit, John Harlow,

12 [REDACTED] ²⁵⁰ [REDACTED]

14 [REDACTED] ²⁵¹

15 367. The Endo and Purdue proposals were essentially identical sales transformations.
 16 The goals were the same: to maximize sales of opioids. Merely the names were changed. While
 17 McKinsey offered to “turbocharge” Purdue’s sales force, McKinsey proposed a “sales force blitz”
 18 for Endo.²⁵²

19 368. In fact, the names weren’t *entirely* changed. [REDACTED]

21 [REDACTED] ²⁵³

22 369. [REDACTED]

26 ²⁴⁸ MCK-MDL2996-0070237.

27 ²⁴⁹ ENDO_AAC_00363406.

28 ²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *E.g.*, MCK-MDL2996-0130803; MCK-MDL2996-0132851.

²⁵³ MCK-MDL2996-0069747, at 0069749.

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[REDACTED]

[REDACTED]

[REDACTED].

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

371. Upon McKinsey's suggestion, Endo began reallocating sales force resources to Opana from other Endo products such as Sumavel, a migraine medication, and Voltaren, an anti-inflammatory.²⁵⁴ Writing to the McKinsey team, Endo's Alicia Logan stated the joint mission, "I agree that our main goal is to maximize the increased promotional efforts for [Opana ER] without

²⁵⁴ MCK-MDL2996-0409466.

1 disrupting/sacrificing [Sumavel] or [Voltaren] TRx volume and it appears that we [can]
 2 accomplish this with your recommendation of addition another 500 targets.”²⁵⁵

3 372. With the Sales Force Blitz underway, Endo received good news in New York.
 4 Years prior, Endo had initiated patent litigation against generic manufacturers of Opana ER,
 5 arguing that the generic versions of the drug infringed on Endo’s patents. In part because of the
 6 perceived impending loss of exclusivity, Endo had in recent years allocated its sales force
 7 capacity away from Opana and to other Endo products.

8 373. On August 14, 2015, Endo received a favorable initial ruling declaring that the
 9 generic versions of Opana violated Endo’s patents, and enjoined their further sale. The ruling
 10 provided additional patent exclusivity for Opana, and Endo was keen to exploit its advantage.

11 374. That afternoon, [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]²⁵⁶

16 375. The following week, Harlow wrote to the McKinsey team working for Endo to
 17 focus their attention on Opana ER. “Now with our litigation victory from last week, plus our
 18 UHC opportunity, there is an increased need to increase FF support to drive Sep-Dec
 19 business. . . . With this win, I am now willing to go broader with OER targeting.”²⁵⁷

20 376. McKinsey and Endo proceeded to design and implement retargeting strategies to
 21 boost Opana sales in late 2015.

22 **2. Johnson & Johnson**

23 377. McKinsey also working with Johnson & Johnson, whose role overseeing and
 24 contributing to the opioid crisis has been exhaustively detailed in other complaints. *See, e.g., City*
 25 *and County of San Francisco v. Purdue Pharma L.P.*, N.D. Cal. No. 18-2591, Doc. 128 (Mar. 13,
 26 2020). Johnson & Johnson occupied multiple roles within the opioids industry. Through its

27 ²⁵⁵ MCK-MDL2996-0409436, at 0409437 (sic).

28 ²⁵⁶ ENDO-OPIOID_MDL-02279530.

²⁵⁷ MCK-MDL2996-0358871, at 0358872; ENDO-OPIOID_MDL-02201117 .

1 subsidiary, Janssen Pharmaceuticals (“Janssen”), it marketed and sold branded opioid products,
 2 including Duragesic (a transdermal fentanyl patch) and Nucynta (tramadol tablets and oral
 3 solution). Through its Noramco and Tasmanian Alkaloids subsidiaries, Johnson & Johnson
 4 farmed the poppy plant in New Zealand and created the precursor chemical and raw materials
 5 necessary to manufacture *all* opioids. Noramco and Tasmanian Alkaloids sold these raw materials
 6 to the other opioid manufacturers: Purdue, Endo, Mallinckrodt, and others. Johnson & Johnson
 7 was the origin point in the entire opioids supply chain.

8 378. Just like McKinsey’s relationships with Purdue, Endo, and the others, McKinsey’s
 9 opioid-related work for Johnson & Johnson spanned decades.

10 379. Just as Endo was led by former partner McKinsey partner Rajiv de Silva, Johnson
 11 & Johnson similarly relied on McKinsey as a pipeline for its own management timber. As
 12 described above, McKinsey alumni tend to move on to positions with McKinsey clients.
 13 Janssen’s current Director of Customer Marketing & Value Based Care was hired from
 14 McKinsey’s PMP group. The relationship flows both ways: Janssen’s former Vice President of
 15 Sales and Marketing for Janssen Pharmaceuticals is currently a McKinsey partner. Moreover, Ian
 16 Davis has been an independent director since 2010 and currently sits on the Audit and Regulatory
 17 Compliance committees of Johnson & Johnson’s board. Previously, he was a Senior Partner at
 18 McKinsey, “having served as Chairman and Worldwide Managing Director from 2003 until
 19 2009.”²⁵⁸

20 380. Kevin Sneader, until recently McKinsey’s global managing partner, and one of
 21 Davis’ successors, described Davis as a “mentor” who was the managing partner of McKinsey’s
 22 London office when Sneader was working there and “worked on one of his teams.”²⁵⁹ Given
 23 Frazier’s presence on the board, Johnson & Johnson was obviously an important account for
 24 McKinsey. At present, it is not known which McKinsey partner(s) was the Director(s) of Client
 25 Services for the Johnson & Johnson account.

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 27 _____
²⁵⁸ <https://www.jnj.com/leadership/ian-e-l-davis>

28 ²⁵⁹ See Interview with Kevin Sneader, Harvard Project for Asian & International Relations, January 31, 2021,
 available at <https://www.youtube.com/watch?v=qed53EGG8kU>

1 381. What is known, however, is that McKinsey [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]”²⁶⁰ On July 6,
 5 2011, Ghatak attended an internal McKinsey call with the consultants working on the Johnson &
 6 Johnson account to discuss the “J&J Nucynta sales force disruption.”²⁶¹ The same day, Laura
 7 Moran, who like Ghatak worked both the Purdue and Endo accounts, also provided internal
 8 advice regarding Nucynta to her McKinsey partner Gerti Pellumbi, who was leading Nucynta
 9 sales efforts for the Johnson & Johnson account, and engagement manager Bryan Reinholt, who
 10 was with Pellumbi on the Johnson & Johnson account.²⁶² Martin Elling, one of the lead
 11 McKinsey partners on the Purdue account alongside Ghatak, attended internal McKinsey calls on
 12 March 25, 2010,²⁶³ and again on May 27, 2011 to discuss McKinsey’s work for Johnson &
 13 Johnson’s Nucynta.²⁶⁴ Then, on December 13, 2011, Elling attended a meeting with Johnson &
 14 Johnson personnel regarding “acceleration opportunities.”²⁶⁵ Aamir Malik attended the meeting
 15 with Elling, and, naturally, also worked on the Endo account.²⁶⁶ Malik and Ghatak had an internal
 16 McKinsey meeting amongst themselves regarding the “Nucynta Kickoff” at Johnson & Johnson
 17 six months prior, on June 3, 2011.²⁶⁷

18 **a. Noramco**

19 382. Janssen was not the only Johnson & Johnson unit [REDACTED]
 20 [REDACTED], and Janssen was not Johnson & Johnson’s only division involved in the
 21 narcotics trade.

25 ²⁶⁰ JAN-NH-00167575.

26 ²⁶¹ MCK-MDL2996-0222833.

27 ²⁶² MCK-MDL2996-0419348.

28 ²⁶³ MCK-MDL-2996-0256186.

²⁶⁴ MCK-MDL-2996-0255907.

²⁶⁵ MCK-MDL-2996-0255926.

²⁶⁶ *Id.*; see also MCK-MDL-2996-0348536 (Example of Malik’s work on Endo account).

²⁶⁷ MCK-MDL-2996-0261694.

383. Opioids—all of them—are derivatives of opium, which is derived from the poppy plant. In order to sell opioids, someone needs to farm the opium poppy and process the harvest into the raw materials necessary for opioid manufacturers—all of them—to make their products.

384. Johnson & Johnson was that farmer. It owned Noramco and Tasmanian Alkaloids, which grew poppies in New Zealand and sold the raw ingredients for opioids to practically all manufacturers.

385. On August 19, 2009, McKinsey's [REDACTED]

[REDACTED]²⁶⁸

386. [REDACTED]

[REDACTED]²⁶⁹

387. Seven years later, in 2016, Johnson & Johnson exited the business by selling Noramco and Tasmanian Alkaloids to SK Capital, a private equity firm focused on the pharmaceuticals business, for approximately \$800 million.²⁷⁰ [REDACTED]

[REDACTED] Not only was McKinsey's advice invaluable to Johnson & Johnson, the perspective McKinsey gained of the overall opioid market from advising the principal upstream supplier to the entire industry would be invaluable in to its own work with its other opioid manufacturer clients.

b. Duragesic

388. Fentanyl was first synthesized by Paul Janssen and his pharmaceutical company Janssen Pharmaceuticals in 1959. In the 1990s, the company (by then owned by Johnson &

²⁶⁸ NORAMCO_TX_01136410.

²⁶⁹ NORAMCO_TX_01136411, slide 4.

²⁷⁰ Gareth Macdonald, "US Investor buys J&J's opiate API business and announces restructuring," *Outsourcing Pharma*, July 20, 2016, *available at*: <https://www.outsourcing-pharma.com/Article/2016/07/21/US-investor-buys-J-J-s-opiate-API-business-and-announces-restructuring>

Johnson) developed Duragesic, which is a transdermal patch that administers fentanyl to the patient wearing it.

389. “Duragesic proved to be one of the most successful analgesic pharmaceutical products ever developed, with sales in 2004 (its last year of patent life) exceeding \$2.4 billion. The success of the fentanyl patch caused many generic companies to produce equivalents once it went off patent.”²⁷¹

390. McKinsey was an integral part of fentanyl’s success. As early as 2002, McKinsey was advising Johnson & Johnson regarding methods to boost sales of its opioids. For example, on March 14, 2002, McKinsey prepared a confidential report for Johnson & Johnson’s subsidiary Janssen regarding how to market their opioid Duragesic. Incredibly, one of the recommendations McKinsey provided to Johnson & Johnson was that they concentrate their sales and marketing efforts on doctors that were *already* prescribing large amounts of Purdue’s OxyContin.²⁷²

391. In other words, as early as 2002, McKinsey had such intricate knowledge of the sales and marketing practices of opioid manufacturers, generally, and Purdue’s efforts with OxyContin, specifically, that it was able to recommend to *a competitor of Purdue* that it boost its own opioid sales by *following in the footsteps of Purdue*.

392. McKinsey also advised Johnson & Johnson to target Duragesic on “high abuse-risk patients (e.g., males under 40).” This targeting would take advantage of the marketing claim that Duragesic “was harder to abuse than other opioids on the market.”²⁷³

393. McKinsey helped Janssen target its opioid marketing by identifying “priority growth opportunities” and growth strategies for Duragesic.²⁷⁴ In 2002, McKinsey considered “[w]hat are settings of care for opioid high-prescribers and treaters of back pain,” listing the

²⁷¹ Theodore Stanley, “The Fentanyl Story,” *The Journal of Pain*, Vol. 15, No. 12 (December), 2014, pg. 1220, available at: [https://www.jpain.org/article/S1526-5900\(14\)00905-5/pdf](https://www.jpain.org/article/S1526-5900(14)00905-5/pdf)

²⁷² Chris McGreal, *Johnson & Johnson faces multibillion opioids lawsuit that could upend big pharma*, *The Guardian*, June 23, 2019, available at: <https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-opioids-crisis-lawsuit-latest-trial>

²⁷³ Julia Lurie, “*Inside Johnson and Johnson’s Quiet Domination of the Opioid Market*,” June 11, 2019, Mother Jones, available at <https://www.motherjones.com/politics/2019/06/johnson-and-johnson-opioid-poppies-tasmania-oklahoma-lawsuit/>

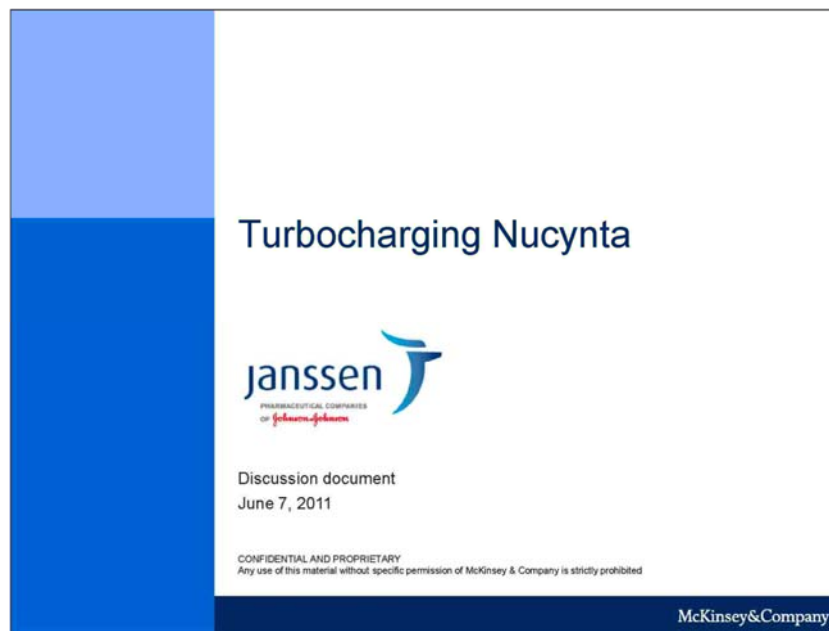
²⁷⁴ *Oklahoma v. Johnson & Johnson*, Oklahoma Proposed Findings & Conclusions, citing 5/30/19pm Tr. & S-1253; see also JAN-MS-00481545 (Deem-Eshleman Ex 73).

“elderly” as an example;²⁷⁵ [REDACTED]

[REDACTED].²⁷⁶

c. Turbocharging Nucynta

394. McKinsey’s infamous Project Turbocharge to boost OxyContin sales at Purdue in 2013 and 2014—the same project detailed in Purdue’s 2020 guilty plea with the Department of Justice—was not McKinsey’s first experience turbocharging opioid sales. Before OxyContin, there was Nucynta:²⁷⁷



395. Nucynta was Janssen’s branded tapentadol product. Tapentadol is generally regarded as a moderately strong opioid. Nucynta was first approved as a Schedule II controlled opioid agonist tablet and oral solution in 2008, and indicated for “relief of moderate to severe acute pain in patients 18 years of age or older.” In 2011, Janssen obtained approval for a long-acting version Nucynta ER, which was indicated for “management of moderate to severe chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.”

²⁷⁵ *Oklahoma v. Johnson & Johnson*, 5/30/19 Tr. At 46:1-15.

²⁷⁶ JAN-MS-00481547 (Deem-Eshleman Ex 74) .

²⁷⁷ MCK-MDL-2996-0135636.

396. McKinsey is a repeat opioid sales turbocharger. McKinsey's efforts to turbocharge Nucynta sales resembled those it later deployed in more robust form at Purdue a few years later. For example, "physician prescribing habits," and "switching behavior," were external factors McKinsey identified as key issues "impacting future Nucynta growth." Understanding these issues at a granular level would be crucial, including "What is physician/market awareness of Nucynta ER? By physician segment?"²⁷⁸ These same factors drove McKinsey's later work turbocharging OxyContin.

397. Along the way, McKinsey [REDACTED]

[REDACTED]²⁷⁹

398. Despite this ambivalence about tamper-resistance, in a status update on June 23, 2011, McKinsey informed Janssen that its "initial physician interview findings" indicate Nucynta ER has "lower addictive/abuse potential and side-effect profile as key differentiators vs. Oxycontin ER."²⁸⁰

399. As part of the turbocharge process, [REDACTED]

[REDACTED]²⁸¹

400. By 2014, Janssen was began exploring the sale of Nucynta, and McKinsey was involved in the process. Incredibly, [REDACTED]

[REDACTED]²⁸² Purdue ultimately did not purchase Nucynta. Instead, in 2015, Johnson & Johnson's

²⁷⁸ MCK-MDL-2996-0135636.

²⁷⁹ JAN-MS-00322271.

²⁸⁰ MCK-MDL-2996-0009526, at 0009529.

²⁸¹ JAN-MS-02272779.

²⁸² PPLPC023000661013 [REDACTED]

1 Janssen unit sold its Nucynta rights to another manufacturer, Depomed Inc., for just over one
2 billion dollars.²⁸³

3 401. The year prior, Nucynta accounted for \$172 million in annual sales for Janssen.
4 Janssen described the Nucynta sale to Depomed as “a strategic decision designed to focus efforts
5 on growth efforts.”²⁸⁴ Depomed, for its part, saw the Nucynta acquisition as a transformational
6 opportunity to position itself as “a pain and neurology-focused specialty pharmaceutical
7 company.”²⁸⁵

8 402. When Depomed bought Nucynta, [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

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16 3. Other Manufacturers

17 403. McKinsey worked with numerous other manufacturers to promote the sale of
18 opioids. To date, Plaintiffs have identified as McKinsey clients [REDACTED]²⁸⁷ and [REDACTED]
19 [REDACTED].²⁸⁸

20 404. Coordination among these industry participants was a natural outgrowth of the fact
21 that McKinsey had existing client relationships with each participant. For instance, on May 7,
22 2009, Richard Sackler’s personal counselor, McKinsey partner Maria Gordian, [REDACTED]
23 [REDACTED]
24 [REDACTED].

²⁸³ See <https://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html>

²⁸⁴ Josh Beckerman, “DepoMed to Buy U.S. Rights to Nucynta From J&J Unit,” *Wall Street Journal*, January 16, 2015, available at: <https://www.wsj.com/articles/depomed-to-buy-u-s-rights-to-nucynta-from-j-j-unit-1421357503>

²⁸⁵ *Id.*

²⁸⁶ DEPO-CDI-00071072 (emphasis added).

²⁸⁷ MNK-MDL_001756041; MNK-T1_0000968026; MN-T1_0004715842; MNK-T1_0005985720.

²⁸⁸ TEVA_CHI_00187019.

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4. McKinsey's Work with Opioid Distributors

407. McKinsey worked with opioid distributor AmerisourceBergen

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408. McKinsey worked with opioid distributor McKesson on the company's

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5. McKinsey's Work with the FDA

409. As described above, McKinsey assisted Purdue and others to confront FDA regulations that posed threats to their clients' ability to maximize revenues from their opioid products. McKinsey's role in shepherding its clients through regulatory interactions takes on a

²⁸⁹ TEVA_CHI_00187019.

²⁹⁰ TEVA_CHI_00187023.

²⁹¹ See ALLERGAN_MDL_00637407.

²⁹² ABDCMDL12135609, slide 5.

²⁹³ MCKSTCT00753097; MCKSTCT00753098.

1 different how when considered in light of one of McKinsey's other clients: the Food and Drug
2 Administration itself.

3 410. Indeed, the FDA has proved a massive client for McKinsey, who since 2000 has
4 endeavored to expand its public sector practice under the direction and leadership of Nancy
5 Killefer, a now-retired senior partner and director of the firm.²⁹⁴ Since 2008, the FDA has paid
6 McKinsey more than \$140 million.²⁹⁵ A significant portion of that work for the FDA related to
7 the FDA's Center for Drug Evaluation and Research ("CDER"). The CDER is the principal
8 division tasked with approving, among other classes of drugs, opioids. Since 2008, McKinsey has
9 been awarded at least 17 contracts worth at least \$48 million for CDER work.²⁹⁶

10 411. The REMS protocols, discussed above, that McKinsey assisted Purdue and others
11 in surmounting beginning in 2008 and culminating in 2012, were overseen by CDER.²⁹⁷

12 412. Meanwhile, in 2010, McKinsey advised the FDA on building a monitoring system
13 called "track and trace" to assist in the identification of potentially improper distribution of
14 harmful prescription drugs, such as opioids. "The 'track and trace' system deeply impacted
15 McKinsey clients, including the nation's three largest drug distributors—McKesson,
16 AmerisourceBergen, and Cardinal Health [where Killefer has been a director since 2015]."²⁹⁸

17 413. Under one contract, McKinsey developed a roadmap and implemented plans to
18 modernize CDER's new drug regulatory program. Under another, McKinsey developed a
19 framework to increase information technology project delivery across CDER.²⁹⁹

20 414. In 2007, Congress passed the Food and Drug Administration Amendments Act
21 ("FDAAA"), which placed new restrictions on the use of certain high risk prescription drugs,
22 including opioids. The new law mandated that FDA require manufacturers of certain drugs to
23 create REMS.

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25 ²⁹⁴ Duff McDonald, *The Firm*. Killefer is also a director of Cardinal Health, one of the distributor defendants in the ongoing nationwide opioid litigation, and a company subject to FDA regulations.

26 ²⁹⁵ Letter to Dr. Janet Woodcock from Senator Margaret Hassan et al, August 23, 2021, *available at*:
https://www.hassan.senate.gov/imo/media/doc/fda-mckinsey_letter-final-210823.pdf ("Hassan Letter")

27 ²⁹⁶ *Id.*

²⁹⁷ *Id.*

²⁹⁸ See <http://cg.cardinalhealth.com/board-of-directors/default.aspx>; Hassan Letter.

28 ²⁹⁹ Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*:
https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

1 415. The FDAAA also required the Secretary of Health and Human Services “to
2 develop standards and identify and validate effective technologies for the purpose of securing the
3 drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded,
4 or expired drugs.” 21 U.S.C. § 355e(a).

5 416. In 2010 and 2011, under the FDAAA, the FDA awarded McKinsey contracts to
6 design a “track and trace” system to monitor prescription drugs, including opioids, throughout the
7 supply chain and to streamline the drug approval process. The track and trace system had the
8 greatest effect on drug distributors, including McKinsey clients McKesson, AmerisourceBergen,
9 and Cardinal Health.³⁰⁰

10 417. Under these contracts, McKinsey was required to consult with “supply chain
11 stakeholders,” which likely included these three McKinsey clients as well as pharmaceutical
12 manufacturers.³⁰¹

13 418. In 2011, McKinsey also won a \$1.8 million contract with CDER’s Office of
14 Surveillance and Epidemiology (“OSE”), which monitors and evaluates the safety profiles of
15 drugs available to American consumers.³⁰² OSE “evaluates more than 2 million adverse event
16 reports submitted every year to FDA’s MedWatch program” and provides “risk management
17 expertise on development and implementation of programs and initiatives to support [CDER’s]
18 policies related to [REMS] authorities.”³⁰³

19 419. The OSE contract tasked McKinsey with a widespread mission of understanding
20 how OSE functions within the context of a broader system of drug safety in CDER and ultimately
21 developing and implementing a new operating model. In other words, McKinsey helped to
22 restructure a key body that has oversight over the opioid supply chain.

23 420. The 2012 Food and Drug Administration Safety and Innovation Act required the
24 FDA to modernize Sentinel, a system meant to monitor the safety of drugs once they are on the
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26 ³⁰⁰ Hassan Letter.

27 ³⁰¹ *Id.*

28 ³⁰² <https://www.documentcloud.org/documents/21071060-mckinsey-ose-contract>

³⁰³ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology>

1 market.³⁰⁴ According to the FDA, “Sentinel generates *real-world evidence* to support regulatory
 2 actions aimed at protecting the public’s health,” which in turn “inform[s] healthcare provider
 3 decision-making for patients.”³⁰⁵

4 421. A 2014 contract with the FDA charged McKinsey with assessing the “strengths,
 5 limitations and appropriate use” of Sentinel. Like the track and trace contract, the Sentinel project
 6 required McKinsey to interview “external stakeholders,” including “industry organizations” and
 7 “drug and device industry leaders.”³⁰⁶ McKinsey also evaluated how the FDA employees used
 8 Sentinel to inform regulatory decision making.³⁰⁷

9 422. McKinsey performed similar work for the FDA as recently as 2019,³⁰⁸ when it
 10 signed a contract extension with the agency for work relating to the FDA’s efforts to modernize
 11 the process by which it regulates new drugs.³⁰⁹

12 423. The FDA’s drug tracking programs have been panned as failures.³¹⁰

13 424. A theme was emerging: as new legislation and regulatory systems were enacted
 14 that could have hampered the opioid supply chain, McKinsey stepped in as a key consultant for
 15 the FDA. Each time, the new system failed to reign in the out-of-control opioid market. While the
 16 FDA was not solely responsible for regulating the opioid industry and McKinsey was not wholly
 17 responsible for the FDA’s inaction, tools like Sentinel and track and trace could have been
 18 implemented in a way to provide new information to combat the country’s growing opioid crisis.

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 20 ³⁰⁴ https://www.documentcloud.org/documents/21071047-r_sentinel_assessment_award_contract_sow-redacted-pr

21 ³⁰⁵ <https://www.fda.gov/files/about%20fda/published/Sentinel-System-Overview—Presentation.pdf>;

22 <https://www.healthaffairs.org/doi/10.1377/hpb20150604.936915/full/>

23 ³⁰⁶ Ian MacDougall, “McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency,” *ProPublica* (Oct. 4, 2021), available at <https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency>

24 ³⁰⁷ Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf>

25 ³⁰⁸ Ian MacDougall, “McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency,” *ProPublica* (Oct. 4, 2021), available at <https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency>

26 ³⁰⁹ Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf>

27 ³¹⁰ Sabrina Tavernise, “F.D.A. Faulted for Problems With Drug Tracking” *The New York Times*, Jan. 14, 2016, available at <https://www.nytimes.com/2016/01/15/health/fda-faulted-for-problems-with-drug-tracking.html>;

28 <https://www.gao.gov/assets/gao-16-192.pdf>

1 425. At the same time it was consulting for the FDA, McKinsey was working with its
2 opioid industry clients on how skirt the FDA's regulatory systems.

3 426. For example, McKinsey advised Purdue on how to soften the FDA's proposed
4 REMS and on coordinating with other opioid manufacturers to advocate against strict
5 oversight.³¹¹ The finalized REMS for opioid products was largely devoid of the restrictions that
6 FDA had initially proposed.³¹²

7 427. McKinsey's work with the FDA was a key factor in why pharmaceutical industry
8 clients tapped McKinsey for FDA-related work. For example, in endorsing McKinsey's proposed
9 strategy of banding together with other opioid manufacturers, Purdue CEO John Stewart
10 suggested that the consultant itself facilitate the pharmaceutical group's approach to FDA. He
11 wrote: "Perhaps a consultant such as McKinsey who did similar work in the industry and FDA on
12 some aspects of clinical trials or a healthcare-related group that would be interested in playing an
13 active role in the program's development and delivery would be a good choice."³¹³

14 428. McKinsey performed work for the FDA without disclosing its potential conflicts
15 of interest to the FDA in violation of the contracts between the company and the agency.

16 429. The FDA typically includes conflict of interest clauses in its contracts and relies on
17 contractors to assess and report any conflicts. McKinsey's contracts with the FDA related to
18 CDER processes contained such provisions. One contract required McKinsey to "make an
19 immediate and full disclosure, in writing, . . . of any potential or actual organizational conflict of
20 interest or the existence of any facts that may cause a reasonably prudent person to question the
21 contractor's impartiality because of the appearance or existence of bias."³¹⁴

26 ³¹¹ Hassan Letter.

27 ³¹² Hassan Letter; Maloney Letter.

28 ³¹³ Purdue Bankruptcy, Doc. 2166-5, at 58-59.

³¹⁴ Ian MacDougall, McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency, *ProPublica* (Oct. 4, 2021), available at <https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency>

1 430. But McKinsey never disclosed its work on behalf of opioid supply clients to the
2 FDA despite having a hand in developing some of the FDA's most important regulatory
3 processes.³¹⁵

4 431. Disclosing its conflicts might have turned off the lucrative tap to not only FDA
5 contracts but also to pharmaceutical industry clients, given the clear value such clients placed on
6 McKinsey's work for the FDA.

7 432. McKinsey's manipulation of regulatory requirements—whether to skirt its own
8 contractual requirements or to bend processes that regulate its clients—is nothing new. McKinsey
9 has come under fire from the Office of Inspector General for the General Services Administration
10 for contract procurement violations³¹⁶ and from the Justice Department related to violation of
11 Chapter 11 bankruptcy rules.³¹⁷ Most recently, six senators have begun to investigate the
12 relationship between McKinsey and the FDA³¹⁸ the House Committee on Oversight and Reform
13 is exploring its abusive conduct in connection with the opioid industry.³¹⁹

14 433. As one commentator noted, McKinsey's conduct suggests that it “behaves as if it
15 believes the rules should bend to its way of doing things, not the other way around.”³²⁰

16 **F. McKinsey's Efforts to Increase the Overall Size of the Opioid Market: the**
17 **Larger the Pie, the Larger the Slice**

18 434. McKinsey advised multiple opioid manufacturers regarding how to grow opioid
19 sales. In order to benefit all its clients, McKinsey engaged in efforts to grow the entire opioid
20 market, and not only each individual client's share of it. The theory, basically, is that a rising tide
21 lifts all boats.

22
23
24 ³¹⁵ *Id.*; Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*:
https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

25 ³¹⁶ Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), *available at*
<https://www.propublica.org/article/how-mckinsey-makes-its-own-rules>

26 ³¹⁷ Mary Williams Walsh and Emily Flitter, McKinsey Faces Criminal Inquiry Over Bankruptcy Case Conduct, *New*
York Times, Nov. 8, 2019, *available at* [https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-](https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-investigation-bankruptcy.html)
27 [investigation-bankruptcy.html](https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-investigation-bankruptcy.html)

28 ³¹⁸ Hassan Letter.

³¹⁹ Maloney Letter.

³²⁰ Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), *available at*
<https://www.propublica.org/article/how-mckinsey-makes-its-own-rules>

1 435. For example, Purdue incentivized its sales staff “to increase not just sales of
 2 OxyContin but also generic versions of extended release oxycodone.” Typically, one would not
 3 wish to encourage the sales of generic competitors that offer a similar product to one’s own. If,
 4 however, the goal is to position a company so as to look like an attractive acquisition target, the
 5 growth of the overall opioid market is just as important as one’s own market share: “Whereas
 6 pharma salespeople are usually compensated based on their ability to grow sales of a particular
 7 medicine, part of the bonus for Purdue’s staff was calculated in relation to the size of the overall
 8 market.”³²¹ McKinsey designed that plan.³²²

9 436. This notion that the size of a company’s market share is not as important as the
 10 size of the *overall* market in which it competes is a core insight of McKinsey’s granular approach
 11 to identifying corporate growth opportunities. Describing their authors’ conclusions in *The*
 12 *Granularity of Growth*, McKinsey stated, “One of their most surprising conclusions is that
 13 increased market-share is seldom a driver of growth. They contend, instead, that growth is driven
 14 by where a company chooses to compete: which market segments it participates in . . . the key is
 15 to focus on granularity, to breakdown big-picture strategy into its smallest relevant
 16 components.”³²³

17
 18
 19
 20 ³²¹ See David Crow, *How Purdue’s ‘one-two’ punch fuelled the market for opioids*, Financial Times, September 9,
 21 2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

22 ³²² Worth noting is that this strategy of increasing overall opioid sales directly benefitted the Sacklers through their
 23 ownership of Rhodes Pharma, a generic opioid manufacturer. Naturally, McKinsey worked with the Sacklers in
 24 connection with Rhodes as well, including proposing ideas for synergizing Purdue and Rhodes. See, e.g., MCK-
 25 MDL2996-0324955; MCK-MDL2996-0285201. Especially worth noting is that this strategy also benefitted
 McKinsey’s other opioid clients as well. As one observer wrote: “They have a huge amount of inside information,
 which raises serious conflict issues at multiple levels,” stated a former consultant, referring to McKinsey’s influential
 role as advisor to multiple participants in a given industry, such as opioid manufacturing. It “puts them in a kind of
 oligarchic position.” Michelle Celarier, *The Story McKinsey Didn’t Want Written*, Institutional Investor, July 8, 2019,
 available at: <https://www.institutionalinvestor.com/article/blg5zjdc97k2y/The-Story-McKinsey-Didn-t-Want-Written>.

26 For example, in an August 15, 2013 presentation to Purdue management entitled “Identifying OxyContin
 27 Growth Opportunities,” McKinsey noted that “McKinsey’s *knowledge of the ways other pharma companies operate*
 suggests Purdue should reassess the roles of MSL and HECON Groups – and further drive the salesforce to be more
 responsive to formulary coverage changes.” (emphasis added).

28 ³²³ *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, available at:
<https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth>

437. In other words, “Purdue’s marketing force was indirectly supporting sales of millions of pills marketed by rival companies.”³²⁴ “It’s the equivalent of asking a McDonald’s store manager to grow sales of Burger King and KFC,” stated a government official with the Department of Health and Human Services.³²⁵

G. McKinsey’s Work Kills People.

438. The deceptive marketing strategies McKinsey developed and helped to implement were successful. Its granular growth tactics, myopically focused on increased revenues for its clients, substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and as of 2016, 20% of office visits for non-cancer pain included the prescription of an opioid.³²⁶

439. In 2009, Dr. Van Zee identified the *precise tactics* that McKinsey deployed for all of its opioid clients, including Purdue, as a source of OxyContin misuse and abuse, and suggested that regulation may be appropriate to curtail the use of the McKinsey’s tactics: “The use of prescriber profiling data to target high-opioid prescribers—coupled with very lucrative incentives for sales representatives—would seem to fuel increased prescribing by some physicians—perhaps the most liberal prescribers of opioids and, in some cases, the least discriminate.”³²⁷

440. In time, additional evidence mounted supporting the conclusion that McKinsey’s tactics were demonstrably exacerbating the nationwide opioid crisis. One way of demonstrating the link between aggressive sales and marketing of opioids and worsened mortality outcomes arose out of a quirk of Purdue’s own marketing tactics.

441. In 1996, when OxyContin was introduced, five states maintained “triplicate” programs that required prescribers of Schedule II controlled substances to fill out prescriptions in

³²⁴ See David Crow, *How Purdue’s ‘one-two’ punch fueled the market for opioids*, Financial Times, September 9, 2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

³²⁵ *Id.*

³²⁶ Deborah Dowell, Tamara M. Haegerich, and Roger Choi, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, CDC (March 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

³²⁷ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 221, 224 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>.

triplicate.³²⁸ One of the triplicate copies would then be filed with the state agency in charge of maintaining a prescription database intended to monitor diversion and other potential issues relating to the over-dissemination of Schedule II narcotics. Because Purdue viewed these triplicate requirements as an overly burdensome hindrance on prescribing, the company chose to focus its marketing efforts in other states that did not impose these constraints.

442. This resource-allocation decision by Purdue to focus more marketing efforts in states with fewer regulations regarding the prescribing of controlled substances provided a way to test whether *marketing* of OxyContin, by itself, was a cause of not only increased overdose rates for OxyContin, but of *all* opioid-related overdoses, *including* those involving illicit opioids such as heroin and fentanyl.

443. The results were stark. In 2019, economists from the University of Pennsylvania, Notre Dame, and the RAND Corporation analyzed the disparate outcomes in overall opioid overdose mortality experienced in the triplicate states where Purdue did not primarily focus its marketing efforts and non-triplicate states where Purdue did primarily focus those efforts.³²⁹

444. The economists found that “OxyContin distribution was about 50% lower in ‘triplicate states’ in the years after the launch. While triplicate states had higher rates of overdose deaths prior to 1996, this relationship flipped shortly after the launch [of OxyContin] and triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years after OxyContin’s introduction. *Our results show that the introduction and marketing of OxyContin explain a substantial share of overdose deaths over the last two decades.*”³³⁰

445. A 2017 *Journal of American Medical Association* study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.³³¹ The changes in prescribing behavior

³²⁸ Patrick Radden Keefe, *Empire of Pain*, Pg. 407.

³²⁹ Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, available at: <https://www.nber.org/papers/w26500>

³³⁰ *Id.* (emphasis added).

³³¹ Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass’n 1785 (2017).

1 appeared strongest at hospitals that implemented the strictest detailing policies and included
 2 enforcement measures. Another study involved the research of four different practices which
 3 included visits by sales representatives, medical journal advertisements, direct-to-consumer
 4 advertising, and pricing, and found that sales representatives have the strongest effect on driving
 5 drug utilization. An additional study found that doctor meetings with sales representatives are
 6 related to changes in doctor prescribing practices and requests by physicians to add the drugs to
 7 hospitals' formularies.

8 446. A more recent *Journal of American Medical Association* study analyzed the
 9 Centers for Medicare and Medicaid Services' Open Payments database regarding pharmaceutical
 10 company marketing efforts towards doctors, as well as CDC data on prescription opioid overdose
 11 deaths and prescribing rates, in order to assess whether pharmaceutical marketing of opioids to
 12 physicians affected the rate of prescription opioid overdose deaths. Notably, the study analyzed
 13 these marketing practices beginning August 1, 2013 and ending December 31, 2015.³³²

14 447. Those dates are significant, as the study captures the same timeframe that
 15 McKinsey's Project Turbocharge, re-christened E2E, was implemented.

16 448. The study noted "physician prescribers are the most frequent source of prescription
 17 opioids for individuals who use opioids nonmedically."³³³

18 449. The study found that "increased county-level opioid marketing was associated
 19 with elevated overdose mortality 1 year later, an association mediated by opioid prescribing rates;
 20 per capita, *the number of marketing interactions with physicians demonstrated a stronger*
 21 *association with mortality* than the dollar value of marketing."³³⁴

22 450. Referring to the sales and marketing tactics McKinsey specialized in
 23 implementing, the authors concluded, "amid a worsening opioid crisis, our results suggest that
 24
 25

26 ³³² Scott E. Hadland *et. al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality*
 27 *from Opioid-Related Overdoses*, JAMA Network, January 18, 2019, *available at*: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720914>.

28 ³³³ *Id.*

³³⁴ *Id.* (emphasis added)

1 industry marketing to physicians may run counter to current efforts to curb excessive opioid
2 prescribing.”³³⁵

3 451. The authors’ proposed solution was plain and simple, and echoed Dr. Van Zee’s
4 congressional testimony from 2002: “Pharmaceutical companies might also consider, as one
5 manufacturer recently did, *voluntarily ceasing marketing opioid products directly to*
6 *physicians.*”³³⁶

7 452. The dangers of opioids were known to McKinsey at the time it engaged in the
8 misconduct described in this Complaint. The addictive potential of opioids and the need for
9 control and restraint in their use was internally understood, as was the likelihood of large-scale
10 opioid addiction, abuse, overdoses, illness, and early death resulting from sharply increased use.

11 453. McKinsey also performed its own research in evaluating the anticipated effects of
12 Project Turbocharge. An April 2014 implementation update observed an increase in sales calls, as
13 well as that “OxyContin [health care providers] with increased calls consistently outperform
14 HCPs with decreasing or no change in call frequency.”

15 454. The evidence of a direct link between increased opioids marketing and sales and
16 increased opioid abuse was everywhere. A 2007 study found “a very strong correlation between
17 therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse.”³³⁷
18 McKinsey evidently understands this. In a September 2016 online article, McKinsey asserts that
19 “[t]here is no doubt that more consistent use of best practices – across geographic areas,
20 institutions, and clinicians – would provide tremendous help in combating the crisis” and
21 describes certain examples of such practices as “successful in reducing prescribing.”³³⁸

22 455. There is a “parallel relationship between the availability of prescription opioid
23 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
24

25 ³³⁵ *Id.*

26 ³³⁶ *Id.* (emphasis added).

27 ³³⁷ Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 *Pharmacoepidemiology and Drug Safety*, 827-40 (2007), available at <https://onlinelibrary.wiley.com/doi/10.1002/pds.1452>.

28 ³³⁸ <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic>

1 associated adverse outcomes.”³³⁹ The opioid epidemic is “directly related to the increasingly
2 widespread misuse of powerful opioid pain medications.”³⁴⁰

3 456. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has
4 quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving
5 opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the
6 CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to
7 reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”³⁴¹

8 457. Compounding the harm from deceptive marketing, McKinsey worked with Purdue
9 to continue and grow the opioid sales of prescribers that raised red flags of diversion, despite
10 Purdue’s legal obligations to report and halt supply. In doing so, it enabled an oversupply of
11 opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids
12 for both patients who could no longer access or afford prescription opioids and addicts struggling
13 with relapse.

14 458. Most of the illicit use originates from prescribed opioids. It has been estimated that
15 60% of the opioids that are abused come, directly or indirectly, through physicians’ prescriptions.

16 459. As McKinsey itself has recognized in citing a study reaching this conclusion,
17 roughly 80% of heroin users previously used prescription opioids.³⁴² As many as one in four
18 patients who receive prescription opioids long-term for chronic pain in primary care settings
19 struggles with addiction. And, the link between prescription narcotic painkiller abuse and
20 subsequent and/or simultaneous heroin abuse continues to grow.

21 460. In fact, people who are addicted to prescription opioid painkillers are 40 times
22 more likely to be addicted to heroin. The CDC identified addiction to prescription pain
23 medication as the strongest risk factor for heroin addiction. A more recent, and even more deadly
24 problem stemming from the prescription opioid epidemic involves fentanyl, a powerful opioid

25 _____
26 ³³⁹ Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med.,
372:241-248 (Jan. 15, 2015).

27 ³⁴⁰ Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Engl. J. Med. (Apr. 14, 2016).

28 ³⁴¹ CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* “Increases in drug and
opioid overdose deaths – United States, 2000–2014.” *American Journal of Transplantation* 16.4 (2016): 1323-1327.

³⁴² <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic>

1 prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into
2 Plaintiffs' communities.

3 461. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in
4 heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary
5 medicine to sedate large wild animals such as elephants, and has been researched as a chemical
6 weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans.

7 462. No demographic is untouched by this epidemic. Nationally, one in five deaths
8 among younger adults in 2016 involved opioids, according to one study. And, deaths involving
9 both prescription and illicit opioids have risen sharply, nearly doubling since 2009.

10 463. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another
11 25% involved heroin. According to the CDC, between 1999 and 2015, more than 183,000 people
12 died in the United States from prescription-related overdoses.

13 464. Rising opioid use and abuse have negative social and economic consequences far
14 beyond overdoses in other respects as well. According to a recent analysis by a Princeton
15 University economist, approximately one out of every three working age men who are not in the
16 labor force take daily prescription pain medication. The same research finds that opioid
17 prescribing alone accounts for 20% of the overall decline in the labor force participation for this
18 group from 2014 to 2016, and 25% of the smaller decline in labor force participation among
19 women. Many of those taking painkillers still said they experienced pain daily.

20 **H. McKinsey Knew that OxyContin Was Highly Abusable, Addictive, and**
21 **Dangerous, and that Its Marketing Strategies Increased Those Harms.**

22 465. McKinsey continued working with Purdue long after the severity of the opioid
23 crisis was well known. McKinsey knew that high dose OyxContin prescriptions carried a serious
24 risk of overdose. In 2017, over half of Purdue's opioids prescriptions exceeded the ninety mg
25 morphine equivalence threshold a day—the recommended maximal dose per the 2016 CDC
26 Guideline for Prescribing Opioids for Chronic Pain.

466. Purdue's 2007 guilty plea put McKinsey on notice of Purdue's misconduct. By that time, McKinsey had access to public information indicating that OxyContin and other opioids pose significant risk of addiction and misuse.

467. McKinsey was well aware of the risks of OxyContin based on its extensive experience in the pharmaceutical industry, close collaboration with Purdue, and participation in the regulatory submissions for reformulated OxyContin.³⁴³

468. The first bullet point of Purdue's 2007 "Observations and Activities Requiring an [Abuse, Diversion, and Detection] Report" was "[a]n apparent pattern of an excessive number of patients for the practice type[.]"³⁴⁴ Thus, McKinsey knew or should have known that there was a higher risk of abuse and diversion among high-volume prescribers.

469. What is more, on September 13, 2013 McKinsey briefed Purdue on the ongoing concerns regarding OxyContin addiction and diversion among prescribers:

Findings on messaging and positioning

PRELIMINARY

- Opioids overall are still viewed as effective and necessary class of painkillers, though side effects and addiction are concerns
- Key themes from prescriber interviews on abuse deterrents include:
 - Prescriber awareness of abuse deterrence and label change is mixed
 - Opinions on impact/efficacy of abuse deterrence vary
 - Most prescribers are concerned about abuse, but attempt to establish measures to protect themselves
 - Concerns remain that technology does not address oral abuse
 - Less informed prescribers ask for additional information and education around abuse deterrent formulations
- Existing market research suggests that most physicians do not feel that reformulation positively impacts their prescribing behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers

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470. In a PowerPoint slide entitled "Findings on messaging and positioning," part of a presentation to Purdue entitled "OxyContin growth opportunities: Phase 1 Final Report:

³⁴³ McKinsey [REDACTED]

PPLPC0390000347612 ([REDACTED])

[REDACTED]; McK-MAAG-0118819 (email chain).

³⁴⁴ PPLPC010000033944.

Diagnostic,” McKinsey noted that “most prescribers are concerned about abuse,” and that “most physicians do not feel that [OxyContin] reformulation positively impacts their prescribing behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers.”

471. In an August 2017 presentation, McKinsey recognized that the opioid epidemic was “triggered, in large part, by a massive increase in prescribed opioids in the early 2000’s.”

472. McKinsey’s presentations to Purdue included extensive discussion of doctors’ concerns about opioid misuse and side effects, demonstrating McKinsey’s awareness of the dangers of opioids. Rather than working to limit these disastrous effects, McKinsey treated doctors’ misgivings as obstacles to confront with new messaging.

473. Indeed, one reason that *Purdue* had knowledge that their own products were addictive and dangerous is because McKinsey told them.

474. If McKinsey was not aware of the adverse consequences of OxyContin, the drug it was paid to sell, such ignorance could not survive the granular reality of its relationship with Purdue. For example, in June 2009, McKinsey worked to “counter the emotional messages from mothers with teenagers that overdosed on OxyContin.”³⁴⁵

475. Within a few years of countering these emotional messages, McKinsey even developed a method to identify geographic hot spots of OxyContin abuse and diversion. Once developed, however, McKinsey simply never used it to decrease these harms.

476. Paul Coplan [REDACTED]

[REDACTED]³⁴⁶

477. In deposition testimony in prior opioid-related litigation, Coplan was asked, “While you were at Purdue, did Purdue make an effort to identify hot spots for opioid abuse and addiction or not?”³⁴⁷

478. “[REDACTED]

³⁴⁵ PDD8901645845.

³⁴⁶ Paul M. Coplan 1/18/19 Dep. Tr. At 16:18 -17:17.

³⁴⁷ *Id.* at 355:10.

1 [REDACTED] 348 [REDACTED]

2 [REDACTED] 349 [REDACTED]

3 479. [REDACTED]

7 [REDACTED] 350 [REDACTED]

8 480. Instead, McKinsey focused on increasing opioid sales for its clients, despite
 9 knowing the harmful consequences of doing so. In yet another indication that OxyContin sales
 10 should not be turbocharged: during McKinsey's work for Purdue, Purdue was unable to purchase
 11 product liability insurance to cover its practice of selling OxyContin.

12 481. The basic premise of McKinsey's work put it on notice of the harmful
 13 consequences that would ensure. It was tasked with advising a monoline manufacturer of opioids
 14 about sales and marketing practices for its addictive products while that manufacturer was bound
 15 by a five-year Corporate Integrity Agreement covering the very same opioid sales and marketing
 16 practices. In 2012, OxyContin accounted for 94% of Purdue's revenue.³⁵¹ As late as 2018, it
 17 remained 84% of Purdue's revenue.³⁵² According to the U.S. Department of Justice, "[f]rom 2010
 18 to 2018, Purdue's profits were almost entirely driven by its success in selling OxyContin."³⁵³ In
 19 2015 alone, it obtained \$3 billion in annual opioid sales—a four-fold increase from its 2006 sales
 20 of \$800 million.

21 482. McKinsey's mandate was to increase Purdue's opioid sales during a time when
 22 Purdue was obligated to restrict its previous marketing strategies because those strategies had
 23 caused the *overprescribing of opioids* and the inevitable consequences thereof. McKinsey's job
 24 was to counter the intended results of the Corporate Integrity Agreement; to devise strategies to
 25

26 ³⁴⁸ *Id.* at 355:14–356:11.

27 ³⁴⁹ *Id.* at 357:8–16.

28 ³⁵⁰ *Id.* at 357:22–358:6.

³⁵¹ Gerald Posner, *Pharma*, pg. 524 (Simon & Schuster 2020).

³⁵² *Id.*

³⁵³ <https://www.justice.gov/opa/press-release/file/1329571/download>

1 sell as many pills as conceivably possible. Under McKinsey's tutelage, Purdue's growth
2 continued its upward trajectory unabated, the Corporate Integrity Agreement notwithstanding.

3 **I. McKinsey Portrays Itself as Part of a Solution to a Problem It was Integral in**
4 **Creating.**

5 483. McKinsey's work on the other side of the aisle—helping clients address opioid
6 abuse and addiction—further proves that it was well aware of the risks of OxyContin, and thus
7 the risks of pushing OxyContin sales and high dose sales, and targeting the highest-volume
8 prescribers. McKinsey advised Purdue on “Project Tango,” a 2014 plan to enter the addiction
9 drug market.³⁵⁴ McKinsey noted the [REDACTED]

10 [REDACTED]”³⁵⁵

11 484. More than assisting specific clients with addressing the crisis itself, McKinsey saw
12 the ongoing opioid crisis as an opportunity to posture itself as contributing more broadly to
13 *society*. McKinsey likes to think of itself as a change agent capable of solving problems that truly
14 matter, and the opioid crisis is one McKinsey realizes matters. Dr. Sarun Charumilind, a
15 McKinsey partner in Philadelphia, “has led the firm's support to clients and *society* to combat the
16 opioid crisis.”³⁵⁶

17 485. In Detroit, partner Razili Lewis also helps “clients and *society* combat the opioids
18 crisis.” She does so by providing “insights, expertise, analytics, and technology.”³⁵⁷

19 486. Over in Cleveland, senior partner Tom Latkovic also “helps clients and *society*
20 combat the opioids crisis.”³⁵⁸

21 487. Kana Enomoto, a senior expert in Washington, D.C., is a “national leader in
22 mental health and substance-use policy,” who acted as a “content director” on a study to “raise
23 awareness about opioid-use disorders.” She also provided strategic guidance to the United States
24

25 _____
26 ³⁵⁴ See David Armstrong, OxyContin Maker Explored Expansion Into “Attractive” Anti-Addiction Market,
ProPublica (Jan. 30, 2019), available at [https://www.propublica.org/article/oxycontin-purdue-pharma-massachusetts-](https://www.propublica.org/article/oxycontin-purdue-pharma-massachusetts-lawsuit-anti-addiction-market)
27 [lawsuit-anti-addiction-market](https://www.propublica.org/article/oxycontin-purdue-pharma-massachusetts-lawsuit-anti-addiction-market).

28 ³⁵⁵ PPLPC023000714734.

³⁵⁶ See <https://www.mckinsey.com/our-people/sarun-charumilind>

³⁵⁷ See <https://www.mckinsey.com/our-people/razili-lewis>

³⁵⁸ See <https://www.mckinsey.com/our-people/tom-latkovic>

1 Surgeon General regarding efforts to “combat the opioid epidemic” when she was his Chief of
2 Staff.³⁵⁹

3 488. McKinsey consistently states that it takes its obligations to society seriously.
4 Indeed, the firm has established a center:³⁶⁰

5 The Center for Societal Benefit through Healthcare was established to build on the
6 long-standing mission of McKinsey’s Public & Social Sector and Healthcare
7 Systems & Services Practices to improve healthcare. The Center’s work is funded
8 solely by McKinsey; it is not commissioned by any business, government, or other
9 institution. The Center brings a range of capabilities to bear, including McKinsey’s
10 healthcare expertise, advanced analytics, functional knowledge, technology assets,
11 network, and investment capacity.

12 The Center aspires to collaborate with other organizations to drive positive
13 innovation to improve overall health and well-being and reduce healthcare
14 disparities.

15 489. The Center has focused on addressing the impacts of the opioid crisis on society.
16 One of the metrics that McKinsey uses to track the opioid crisis *as a matter of public health* is the
17 “opioid prescribing rate” per 100 people in every county in the United States.³⁶¹

18 490. As McKinsey’s data visualization makes clear, there is an association between
19 areas with higher opioid prescribing rates and higher instances of opioid use disorder.

20 491. The Center’s data visualization is also reminiscent of similar work McKinsey did
21 for Purdue in 2013, although the analysis McKinsey did for Purdue was more granular, analyzing
22 opioid prescribing patterns on the *zip-code* level in all 50 states, as opposed to the county level:³⁶²

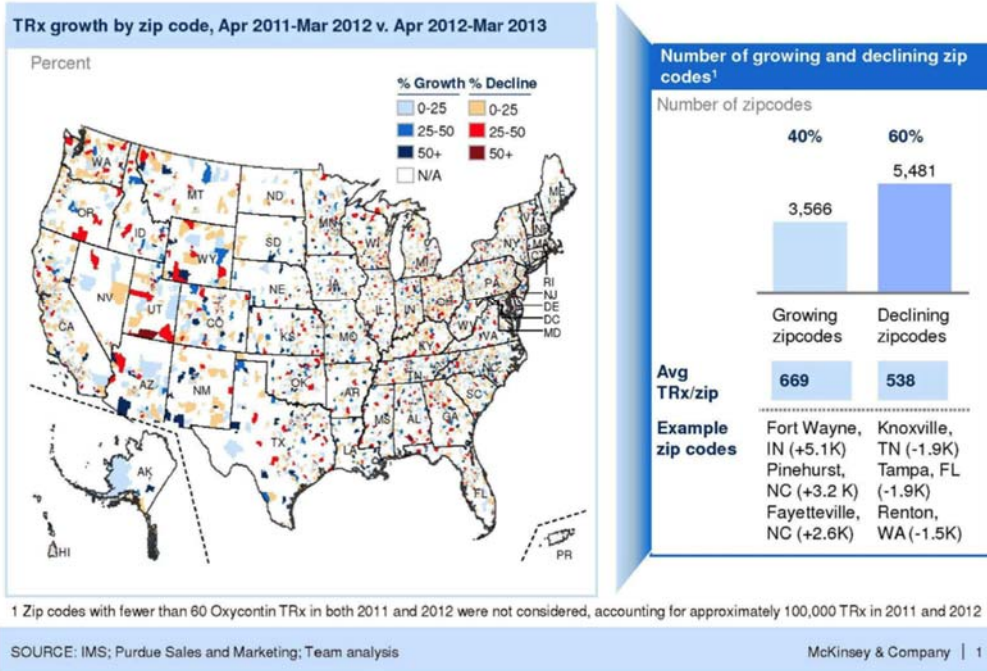
23
24
25
26 ³⁵⁹ See <https://www.mckinsey.com/our-people/kana-enomoto>

27 ³⁶⁰ See <https://www.mckinsey.com/industries/healthcare-systems-and-services/how-we-help-clients/center-for-societal-benefit-through-healthcare/overview>

28 ³⁶¹ See [https://csbh-dashboard.mckinsey.com/#/data-](https://csbh-dashboard.mckinsey.com/#/data-insights?chart=SC&geo=County&lob=All&metric1=opioid_rxrate&metric2=oud&tab=Map)

[insights?chart=SC&geo=County&lob=All&metric1=opioid_rxrate&metric2=oud&tab=Map](https://csbh-dashboard.mckinsey.com/#/data-insights?chart=SC&geo=County&lob=All&metric1=opioid_rxrate&metric2=oud&tab=Map)

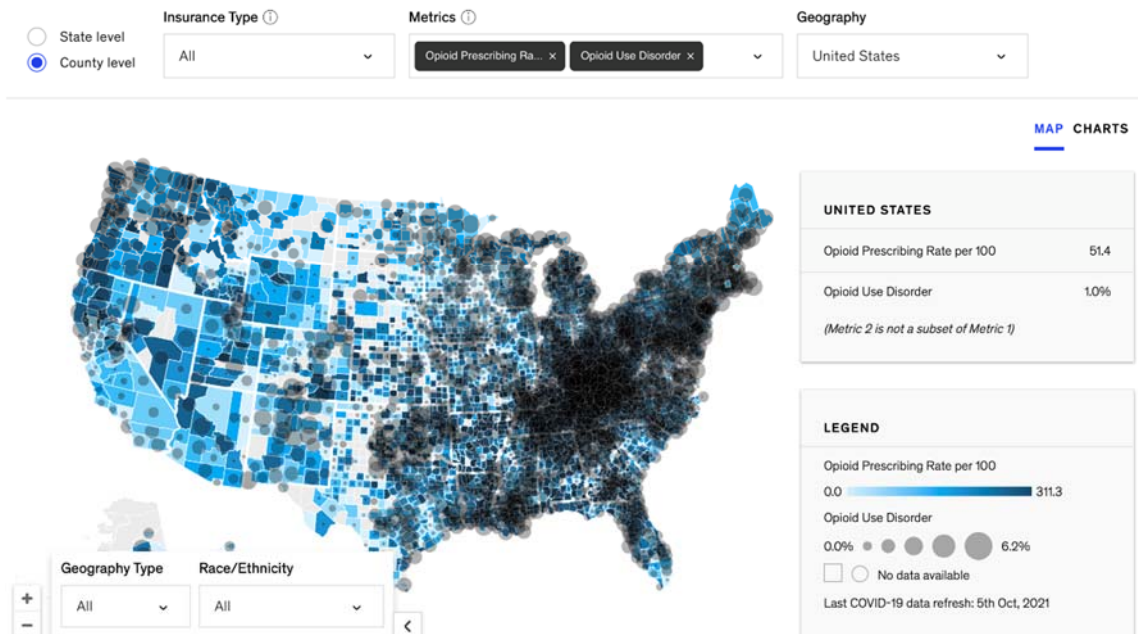
³⁶² MCK-MAAG-0024283.

Exhibit 1: OxyContin growth by geography

492. In other words, the “opioid prescribing rate” was a metric McKinsey worked with its client to boost for years. Now McKinsey measures the extent of the crisis by the same metric:

Vulnerable Populations: Data By Geography

Explore state and county-level data on the distribution of populations with serious underlying physical conditions, behavioral health conditions, long-term care needs, maternal health needs or unmet social needs.



493. Meanwhile, McKinsey has partnered with Shatterproof, a national non-profit organization dedicated to reversing the addiction crisis in the United States, to prepare a report on overcoming stigma associated with opioid use disorder.³⁶³ McKinsey touts the Shatterproof partnership on its webpage as an example of “our societal impact.”³⁶⁴

494. In August 2017, McKinsey prepared a presentation entitled “Perspectives on Combatting the Opioid Crisis,” which referenced its work on combatting opioid addiction for various other entities:

RECENT CLIENT EXPERIENCE

- » Designed and helped launch a health home program to expand resources and accountability for **substance abuse treatment**
- » Conducted a **state wide assessment of opioid prescriber performance** in terms of prescribing rate, dosage, and duration
- » Defined clinically relevant opioid quality measures for a **portfolio of episodes-of-care**
- » Defined clinically relevant opioid quality measures for a **Patient Centered Medical Home and Accountable Care Organizations**
- » Used predictive analytics to develop multi-faceted approach to **assess patient risk** for opioid addiction
- » Used geo-spatial and social network analytics to **assess intensity of opioid abuse and treatment needs**
- » Integrated claims and PDMP data to **generate transparency on provider prescribing practices**
- » Developed a **substance abuse episode of care** focused on priority patient journeys

495. In June 2018, Dr. Charumilind and Mr. Latkovic, along with fellow McKinsey partner Elena Mendez-Escobar, published a public report, “Ten insights on the Opioid crisis from claims data analysis,” stating information about the risks of opioids that McKinsey knew while advising Purdue to sell more opioids and higher dose opioids, and target the highest volume prescribers:

a. “Providers frequently prescribe opioids to patients with known or potential risk factors for abuse[;]”

³⁶³ See <https://www.shatterproof.org/sites/default/files/2020-07/A-Movement-to-End-Addiction-Stigma.pdf>

³⁶⁴ See <https://www.mckinsey.com/us/our-societal-impact>

b. “Approximately 35% of the patients given opioid prescriptions in our analysis had features that put them at increased risk for opioid abuse[.]”

c. “Most opioids are prescribed by providers other than the natural ‘quarterback’ of a patient’s underlying complaint or condition. . . . This finding makes clear that high-dose prescribers and multi-prescriber patterns are separate issues—and both are important to address[.]” and

d. “A small portion of opioid use originates in emergency departments.”³⁶⁵

496. Two months later, the same authors, joined by Ms. Lewis, published “Why we need bolder action to combat the opioid epidemic.”³⁶⁶ “Our research suggests that much broader – and bolder – action is required,” they announced.³⁶⁷

J. Coda

497. Marvin Bower, the McKinsey legend who admonished, “Deliver bad news if you must, but deliver it properly,” died in 2003, one year before the firm began working with Purdue.

498. McKinsey’s work with Purdue would have been unrecognizable to Bower, one of the founders of modern management consulting. Instead of acknowledging the elephant in the room—that Purdue’s business was knowingly maximizing the amount of addictive and deadly opioids sold in the United States—and delivering that bad news promptly properly to the client, McKinsey instead committed to partner with Purdue to maximize opioid sales without regard to the consequences.

499. On October 23, 2017, the president of the United States declared the ongoing nationwide opioid epidemic a “public health emergency.” Even at this late hour in the crisis, McKinsey continued to propose solutions to the Sacklers and Purdue to further boost opioid sales. These solutions were fashioned, in perfect McKinsey parlance, as “high impact interventions to rapidly address market access challenges.”

³⁶⁵ <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/ten-insights-on-the-us-opioid-crisis-from-claims-data-analysis>

³⁶⁶ See <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic>

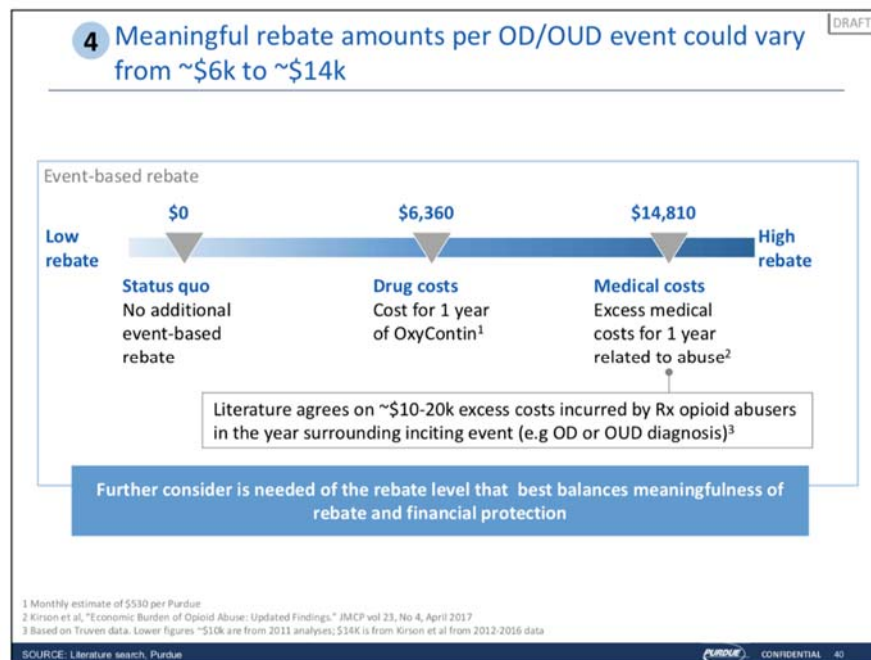
³⁶⁷ *Id.*

500. Less than two months after the public health emergency declaration, McKinsey proposed these high impact interventions to Purdue and its board. Among them was perhaps McKinsey's most audacious gambit of the entire Purdue relationship: paying money—"rebates"—to health insurers whenever someone overdosed on Purdue's drug.

501. These payments for future OxyContin overdoses were christened "Event-Based contracts."³⁶⁸

502. Helpfully, McKinsey provided estimates for the future costs of these "events."³⁶⁹ McKinsey noted that, if Purdue were to start making overdose payments, it would "need to determine which payment amount is optimal."

503. A "meaningful" amount, according to McKinsey, would be somewhere between six and fifteen thousand dollars for each person who overdoses or develops opioid-use disorder as a result of Purdue's drugs:



³⁶⁸ "Consultant-ese," when applied to work as grim as maximizing opioid sales in the face of a national disaster, led one former McKinsey consultant to state: "This is the banality of evil, M.B.A. edition." Walt Bogdanich and Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, New York Times, November 27, 2020, available at: <https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html>

³⁶⁹ McKinsey defined an "event" as "first occurrence for overdose or opioid use disorder."

504. The money would be paid to health insurers for the increased costs of additional medical services that resulted from the fact that Purdue's medications caused opioid-use disorder and overdoses in people whose health care costs were the payors' obligation. The money McKinsey proposed Purdue pay out in these circumstances would not go to the individuals afflicted, nor the estates of the dead.

505. McKinsey's analysis also suggested that it could predict the number of people who would become addicted to opioids or overdose on pills sold through Purdue's downstream customers. McKinsey "projected that in 2019, for example, 2,484 CVS customers would either have an overdose or develop an opioid use disorder."³⁷⁰

506. It is little surprise, then, that McKinsey was concerned with its legal liability for this work. Within months of recommending "event-based contracts" to Purdue, Martin Elling raised this concern with Arnab Ghatak and suggested corrective action: destroying evidence.

Message

From: Martin Elling [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B33C3264F744B04AF05FA59341271BE-MARTIN ELLI]
Sent: 7/4/2018 12:10:13 PM
To: A G [drarnabghatak@gmail.com]
Subject: Re: [EXT]Re: Howdy

Have a great fourth. M

> On Jul 4, 2018, at 2:01 PM, A G <drarnabghatak@gmail.com> wrote:

>
 > Thanks for the heads up. Will do.

>
 >> On Jul 4, 2018, at 7:57 AM, Martin Elling <martin_elling@mckinsey.com> wrote:

>>
 >> Just saw in the FT that Judy Lewent is being sued by states attorneys general for her role on the Purdue Board. It probably makes sense to have a quick conversation with the risk committee to see if we should be doing anything other than eliminating all our documents and emails. Suspect not but as things get tougher there someone might turn to us. M

>>
 >> +=====+
 >> This email is confidential and may be privileged. If you have received it
 >> in error, please notify us immediately and then delete it. Please do not
 >> copy it, disclose its contents or use it for any purpose.
 >> +=====+

507. Elling's prediction that things would "get tougher" for Purdue would prove prescient.

³⁷⁰ Walt Bogdanich and Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, N.Y. Times (Nov. 27, 2020, updated Dec. 17, 2020), <https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html>

1 **1. Guilty Again - 2020**

2 508. On October 20, 2020, Purdue—McKinsey’s co-conspirator—agreed with the
3 United States Department of Justice to plead guilty to improper marketing of OxyContin and
4 other opioids again (the “2020 Settlement Agreement”). This time the plea agreement concerned
5 conduct from 2010 to 2018. The agreement includes \$8.3 billion in penalties from Purdue and
6 \$225 million from the Sackler family.

7 509. Purdue pleaded guilty to a dual-object conspiracy to defraud the United States and
8 to violate the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 353, violating anti-kickback laws,
9 and “using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids—
10 frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged
11 America for decades.”

12 510. The new plea agreement does not identify Purdue’s co-conspirators, and
13 McKinsey is not identified by name in the agreement. Instead, McKinsey is referred to as the
14 “consulting company.”

15 511. Purdue’s new guilty plea concerns Covered Conduct (as defined in the plea
16 agreement) that directly implicates McKinsey in the conspiracy. It is the same conduct described
17 in this Complaint.

18 512. Indeed, the plea agreement signed by McKinsey’s co-conspirator states bluntly:
19 “Purdue, *in collaboration with [McKinsey]*, implemented many of [McKinsey’s]
20 recommendations.” (emphasis added).

21 513. Further, Purdue admitted that E2E “*was overseen by [McKinsey]* and some of
22 Purdue’s top executives through the creation of the E2E Executive Oversight Team (‘EOT’) and
23 Project Management Office (‘PMO’)” (emphasis added).

24 **2. A Mea Culpa**

25 514. On December 5, 2020, six weeks after Purdue’s second guilty plea, McKinsey
26 issued a rare public statement regarding its work with a specific client on its website. The client
27 was Purdue, and the statement was issued in response to Purdue’s second guilty plea and recent
28 media reports regarding McKinsey’s work selling OxyContin after 2007:

McKinsey statement on its past work with Purdue Pharma

December 5, 2020—As we look back at our client service during the opioid crisis, we recognize that we did not adequately acknowledge the epidemic unfolding in our communities or the terrible impact of opioid misuse and addiction on millions of families across the country. That is why last year we stopped doing any work on opioid-specific business, anywhere in the world.

Our work with Purdue was designed to support the legal prescription and use of opioids for patients with legitimate medical needs, and any suggestion that our work sought to increase overdoses or misuse and worsen a public health crisis is wrong. That said, we recognize that we have a responsibility to take into account the broader context and implications of the work that we do. Our work for Purdue fell short of that standard.

We have been undertaking a full review of the work in question, including into the 2018 email exchange which referenced potential deletion of documents. We continue to cooperate fully with the authorities investigating these matters.

515. As the statement indicates, McKinsey stopped doing work “anywhere in the world.” Given that Purdue’s operations addressed only the United States, the global reach of McKinsey’s regret is noteworthy.

516. In August 2013, when the Sacklers adopted McKinsey’s “Project Turbocharge” for Purdue, Tim Reiner, a long-time McKinsey consultant, joined Mundipharma. Mundipharma is a separate company—also owned by the Sacklers—that sells opioids internationally.

517. As late as 2019, Mundipharma has been asserting many of the same misleading claims about opioids that previously led to criminal liability in the United States.³⁷¹ McKinsey has long assisted the Sacklers in growing Mundipharma’s opioids market.³⁷² By 2015, McKinsey’s workload with Mundipharma was large enough to merit formal coordination and incorporation with the overall McKinsey team servicing the Purdue account. Around this time, McKinsey’s Elling agreed to assume “a real operational DCS” role with respect to the work that McKinsey was performing for the various Sackler interests, including “integrat[ing] the Mundipharma

³⁷¹ See Kinetz, Erika, *Fake doctors, pilfered medical records drive OxyChina sales*, Associated Press, November 19, 2019, available at: <https://apnews.com/article/4122af46fdb42119ae3db30aa13537c>

³⁷² See, e.g., MCK-MDL2996-0256120; MCK-MDL2996-0327127; MCK-MDL2996-0183279; MCK-MDL2996-0238998; MCK-MDL2996-0286490.

stuff.”³⁷³ Even if the various components of the Sackler “family conglomerate” were nominally independent, McKinsey consolidated its own treatment of its work for all of these companies as serving just a single client.

3. A Hedge Fund

518. On February 4, 2021, forty-nine state attorneys general announced a multistate settlement with McKinsey related to its work for opioid manufacturers. McKinsey agreed to pay almost \$600 million dollars. At the time of the announcement, most of the participating states each filed a complaint and consent decree finalizing the settlement.

519. Three days after the settlement, it came to light that McKinsey appears to have benefitted from its work promoting opioids not only through the fees paid to McKinsey by its clients, but also through investments in opioid-related business made by McKinsey’s own hedge fund, the McKinsey Investment Office (“MIO”). MIO is the hedge fund referenced above, with respect to McKinsey’s investment in Teva Pharmaceutical.

520. Consultants don’t typically have in-house hedge funds overseeing retirement accounts and partners’ personal investments. In fact, McKinsey is the only one. “Most large companies, including all the major consulting firms, hire third-party firms . . . to oversee their employees’ retirement accounts.”³⁷⁴ MIO manages approximately \$31 billion on behalf of McKinsey partners, employees, and former partners.³⁷⁵

521. Through MIO, McKinsey was heavily invested in the opioid industry, and stood to gain financially from the continuation of the opioid crisis. It even invested in opioid addiction treatment businesses—a growing industry, as McKinsey knew.

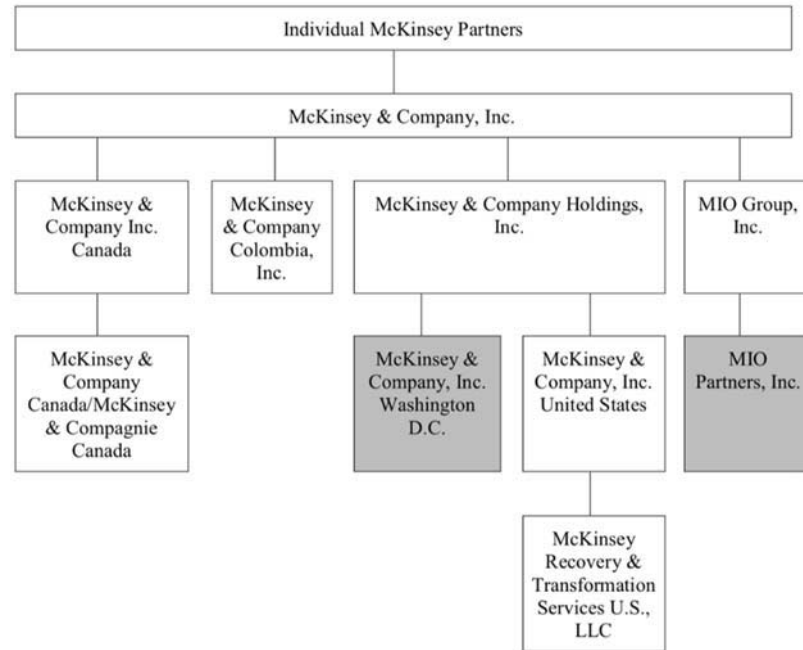
³⁷³ MCK-MDL2996-0210149

³⁷⁴ Gretchen Morgenson, “Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts,” *NBC News*, February 8, 2021, *available at* <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>

³⁷⁵ SEC Order dated November 19, 2020 at Para. 5, *available at*: <https://www.sec.gov/litigation/admin/2021/ia-5912.pdf>. That \$31 billion under management would make MIO Partners the thirteenth largest hedge fund on Earth. *See* <https://www.pionline.com/interactive/largest-hedge-fund-managers-2021>.

522. In short, “during the years McKinsey was helping opioid makers propel sales of the drugs, MIO Partners held stakes in companies that profited from increased usage.”³⁷⁶

523. To understand MIO, an organizational chart of McKinsey is helpful:



524. MIO Group, Inc., and MIO Partners, Inc. are directly-owned subsidiaries of McKinsey & Company, Inc. Given that McKinsey advises countless large corporations, McKinsey’s hedge fund inevitably invests in McKinsey’s clients.

525. MIO manages money for pension plans sponsored by McKinsey in which current and former McKinsey employees participate, as well as privately-offered investment funds available to partners and former partners. Today, nine of MIO’s eleven directors are current or former McKinsey partners. Prior to 2017, there were no outside directors at MIO.

526. MIO structures its investment activities in three principal ways: (1) approximately 50-60% of MIO’s assets are managed by third-party money managers, who have sole discretion on what securities to buy with MIO’s money, and where MIO may or may not have information regarding which securities the third-party money manager has purchased for MIO’s benefit; (2)

³⁷⁶ Gretchen Morgenson, “Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts,” *NBC News*, February 8, 2021, available at <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>

1 “separately managed accounts,” comprising approximately 40% of MIO’s holdings, are portfolios
 2 of securities managed by a third-party money manager, but where MIO “knows what securities
 3 are held through each account,” and; (3) direct investments, where MIO invests its own money
 4 directly, which comprises approximately 10% of MIO’s investments.

5 527. In other words, for *at least 40%* of MIOs holdings, McKinsey partners are able to
 6 know the specific investments held by the various MIO funds. “MIO has a ledger for every
 7 security in their managed accounts.”³⁷⁷ That comprises a pool of capital worth more than \$6
 8 billion.

9 528. MIO is run for the benefit of McKinsey’s partners and, to a separate extent,
 10 McKinsey’s employees. Those individuals (and, crucially, former McKinsey partners) invest their
 11 own money in MIO, and their access to those investment opportunities constitutes a meaningful
 12 and important component of those individuals’ compensation. MIO has, “at a minimum, the
 13 ability to view the individual securities that account for approximately 40 to 50 percent.” This is
 14 approximately \$6 billion dollars of invested capital. What is more, MIO *directly invests*
 15 approximately 10% of its assets. That is \$1.5 billion MIO directly invests in securities without the
 16 use of any outside money manager. These numbers exclude leverage.

17 529. From a conflicts perspective, the fact that *former* partners may participate in MIO
 18 investments merits consideration. With respect to McKinsey’s opioid investments, it is notable to
 19 consider just who some of those “former partners” are. As noted above, Rajiv de Silva, Chief
 20 Executive Officer of opioid defendant Endo Pharmaceuticals, is a former McKinsey partner. Kare
 21 Shultz, Chief Executive Officer of opioid defendant Teva Pharmaceutical, is a former McKinsey
 22 partner. Frank Scholz, President of opioid defendant SpecGX, a subsidiary of Mallinckrodt, is a
 23 former McKinsey partner. Marc Owen, President of opioid defendant McKesson, is a former
 24 McKinsey partner. This list is merely illustrative; it is not exhaustive.

25 530. The result is the prospect of individual executives at various opioid manufacturing
 26 and distribution companies obtaining financial gain from the ongoing propagation of the opioid

27
 28 ³⁷⁷ Michelle Celarier, *McKinsey’s Managed Accounts Come Under Scrutiny in Trial*, Institutional Investor, February
 5, 2020, *available at*: [https://www.institutionalinvestor.com/article/b1k6wnn251s472/McKinsey-s-Managed-](https://www.institutionalinvestor.com/article/b1k6wnn251s472/McKinsey-s-Managed-Accounts-Come-Under-Scrutiny-in-Trial)
 Accounts-Come-Under-Scrutiny-in-Trial

1 crisis *not* via compensation from their employers, but via participating in investments alongside
2 their *former* employer (and, in many cases, current consultant).

3 531. Three days after McKinsey and the state attorneys general announced their
4 settlement, NBC News reported that MIO, McKinsey’s hedge fund, owned opioid-related
5 investments during the time that it advised its opioid clients.

6 532. One is Deerfield Management Co., “a \$10 billion dollar health care investment
7 firm based in New York.”³⁷⁸ As ever, “two top Deerfield executives previously worked at
8 McKinsey.” A retirement fund managed by MIO held a \$108 million stake in funds managed by
9 Deerfield and invested in opioid industry participants. “In 2017, for example, Deerfield was a 6
10 percent shareholder in Mallinckrodt, a major opioid maker.”³⁷⁹ From 2011 through 2016,
11 Deerfield held a stake of up to \$90 million in Teva. Deerfield also took stakes in the distributors
12 described above, including McKesson and Cardinal Health.³⁸⁰

13 533. McKinsey is also invested in treatment, an inevitable growth industry sprouting
14 from the over-selling of opioids. Separate from its investments with Deerfield, MIO is also
15 invested in Adamis Pharmaceuticals, “a company that develops products to treat opioid
16 overdoses,” and therefore “may also benefit from opioid settlement funds” paid by McKinsey as a
17 result of its settlement with the states. As of 2020, MIO owned 26% of the Adamis’ preferred
18 shares through another outside investment manager (not Deerfield).³⁸¹ Separately, Deerfield
19 invested \$331 million in Recovery Centers of America, an addiction treatment company that
20 operates facilities in states that McKinsey recently settled with.³⁸²

21 534. These relationships and investments give a glimpse into the myriad means
22 McKinsey deploys to make money. Consulting is more than giving advice. Indeed, On November
23 19, 2021, MIO Partners agreed to pay an \$18 million fine to the SEC due to MIO’s possession of
24 material nonpublic information related to its holdings, information obtained through consulting.

25 _____
26 ³⁷⁸ Gretchen Morgenson, “Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit
27 from treating addicts,” *NBC News*, February 8, 2021, *available at* [https://www.nbcnews.com/news/us-](https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969)
28 [news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969](https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969)

³⁷⁹ *Id.*

³⁸⁰ *Id.*

³⁸¹ *Id.*

³⁸² *Id.*

1 **VI. TOLLING OF STATUTES OF LIMITATIONS**

2 535. McKinsey is equitably estopped from relying upon a statute of limitations defense.
 3 Alongside its clients, McKinsey undertook active efforts to deceive the Plaintiffs and to
 4 purposefully conceal its unlawful conduct and fraudulently assure the public, including Plaintiffs,
 5 that opioids were non-addictive, effective, and safe for the treatment of long-term chronic pain
 6 and non-acute, non-cancer pain with the goal of increased sales, greater availability and access to
 7 opioids, and maximizing profits.

8 536. McKinsey and its clients were deliberate in taking steps to conceal their
 9 conspiratorial behavior and active role in the deceptive marketing of opioids. This deceptive
 10 marketing—which included the above falsehoods that opioids were safer, less subject to abuse,
 11 and less addictive than other pain medications—was a substantial factor in the oversupply of
 12 opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

13 537. McKinsey deliberately advised its clients on marketing strategies and tactics to
 14 bolster their opioid products as non-addictive, safe, and efficacious without reliable scientific
 15 evidence to support same. McKinsey's consulting services were given confidentially, and both
 16 McKinsey and its clients concealed the content of those services from the public. In doing so,
 17 McKinsey concealed its role in shaping, editing, and providing the content of the false and
 18 misleading materials addressing pain management and opioids that were widely disseminated to
 19 regulators, prescribers, and the public at large, including Plaintiffs.

20 538. McKinsey also concealed from Plaintiffs the existence of the Plaintiffs' claims by
 21 hiding it and its client's lack of cooperation with law enforcement. For example, in May 2007,
 22 Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in
 23 what the company acknowledged was an attempt to mislead doctors about the risk of addiction
 24 and entered into a Corporate Integrity Agreement explained above. Purdue was ordered to pay
 25 \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was
 26 misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science.
 27 Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge
 28 and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty

1 and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled
2 guilty as well and agreed to pay \$7.5 million in fines.

3 539. Nevertheless, even after the guilty pleas, Purdue continued to pay doctors on
4 speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund
5 seemingly neutral organizations to disseminate the message that opioids were non-addictive as
6 well as other misrepresentations. Purdue also assembled an army of lobbyists to fight any
7 legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other
8 painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on
9 lobbying and political contributions—eight times what the gun lobby spent during that period.
10 McKinsey participated extensively in these actions and provided Purdue with strategies and
11 assistance to maximize sales as described in this Complaint. McKinsey knew that the actions it
12 took with Purdue were unlawful, and yet deliberately proceeded in order to increase Purdue's
13 sales and profits, and in turn to serve McKinsey's financial interests.

14 540. McKinsey affirmatively sought to convince the public that its clients' legal duties
15 to report suspicious sales of opioids had been satisfied through public assurances that they were
16 working to curb the opioid epidemic. For example, after the 2007 Purdue guilty plea described
17 above, McKinsey provided services to protect the company's public image and sales, aiding in
18 the concealment of the addictive nature and dangers associated with opioid use and denying
19 blame for the epidemic, attributing it instead solely to abuse and inappropriate prescribing. At the
20 guidance and advice of McKinsey, Purdue and other McKinsey clients publicly portrayed
21 themselves as committed to working diligently with law enforcement and others to prevent
22 diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises
23 to change their ways, insisting they were good corporate citizens. Instead, McKinsey assisted
24 Purdue, for example, with marketing campaigns and messaging that continued business as usual,
25 indiscriminately targeting high prescribers and promoting opioids as safe but avoiding the pitfalls
26 of the Corporate Integrity Agreement. These repeated misrepresentations misled regulators,
27 prescribers, and the public, including the Plaintiffs, and deprived Plaintiffs of actual or implied
28 knowledge of facts sufficient to put the Plaintiffs on notice of potential claims.

541. Plaintiffs did not discover the nature, scope, and magnitude of McKinsey's misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

542. Prior to the applicable limitations period, Plaintiffs did not suspect, and had no reason to suspect, that McKinsey's conduct caused their injuries, including the consumption of Plaintiffs' resources as the opioid epidemic remains unabated.

543. McKinsey intended that its actions and omissions made with its clients would be relied upon, including by the Plaintiffs. The Plaintiffs did not know and did not have the means to know the truth due to McKinsey and its clients' actions and omissions.

544. The Plaintiffs reasonably relied on the affirmative statements developed by McKinsey and made by its clients regarding their purported compliance with their obligations under the law and consent orders, which were false and only intended to save the clients' public image.

545. McKinsey's fraudulent concealment has tolled the running of any statute of limitations. Through it and its clients' affirmative misrepresentations and omissions, McKinsey actively concealed from Plaintiffs the risks associated with opioids that led to the opioids crisis. The wrongdoing, misrepresentations, and omissions by McKinsey has not ceased because the public nuisance remains unabated.

VII. HARM CAUSED TO NAS PLAINTIFFS

A. Neonatal Abstinence Syndrome and Its Results

546. Neonatal abstinence syndrome, also called neonatal opioid withdrawal syndrome ("NOWS"), is a group of conditions caused when babies withdraw from certain drugs, most commonly opioids, they're exposed to in the womb before birth. When a pregnant person takes opioids during pregnancy, the drugs pass through the placenta and cause serious problems for a fetus.

547. Opioid misuse during pregnancy is associated with increased risk of placental abruption, preterm labor, maternal obstetric complications, and fetal death.

1 548. Infants born with NAS often exhibit symptoms of opioid withdrawal including
2 tremors, seizures, overactive reflexes and tight muscle tone; fussiness, excessive crying or having
3 a high-pitched cry; poor feeding or sucking or slow weight gain; breathing problems; fever,
4 sweating, or blotchy skin; trouble sleeping and lots of yawning; diarrhea or vomiting; and stuffy
5 nose or sneezing.

6 549. Infants born with NAS may be treated with medications such as morphine,
7 methadone, or buprenorphine to manage withdrawal symptoms.

8 550. Babies with NAS are more likely to require treatment in the neonatal intensive
9 care unit (“NICU”).

10 551. They are also at increased risk of being born prematurely, low birthweight,
11 jaundice (which is evidence of liver problems), seizures, respiratory issues, sudden infant death
12 syndrome, and other birth defects.

13 552. The effects of NAS are often measured using the Finnegan Scale, which assesses
14 the most common signs of NAS. A high score indicates clinically significant withdrawal and that
15 the infant might be a candidate for medication assisted treatment.

16 553. Children born with NAS are also likely to experience long-term issues including
17 developmental delays, motor problems, behavior and learning problems, emotional disorders and
18 other psychological symptoms, speech and language problems, sleep issues, ear infections, and
19 vision problems.

20 554. The incidence of NAS has been increasing in the United States. Opioid use among
21 women who gave birth increased from 1.19 to 5.63 per 1,000 hospital births between 2000 and
22 2009. During the same period, the incidence of NAS among newborns increased from 1.20 to
23 3.39 per 1,000 hospital births. Another study estimated a ten-fold increase in the number of
24 infants with NAS and were admitted to the NICU from 2005 to 2011.

25 555. It is widely reported that, every 15-25 minutes in the United States, a newborn is
26 diagnosed with NAS due to fetal opioid exposure, and these newborns will likely to fail to thrive
27 both during childhood and as adults.
28

1 556. There are increased costs associated with NAS births and treatment of the effects
2 of NAS.

3 557. For example, a study estimated the costs associated with an NAS birth to be
4 \$53,400 in 2009, compared to \$9,500 for a non-NAS birth. Much of this costs is due to an
5 average hospital stay of 16 days for an infant with NAS.³⁸³

6 558. Due to in utero exposure to opioid drugs marketed by McKinsey and its clients, all
7 Minor Plaintiffs have the right to sue, through their legal guardians, for damages. Further, they
8 are entitled to recover for past and continuing damages including:

9 a. Costs for providing treatment of infants born with opioid-related medical
10 conditions like NAS;

11 b. Equitable relief of medical monitoring, testing, and treatment for latent
12 diseases associated with NAS;

13 c. Costs for providing ongoing medical monitoring care into a Court
14 administered fund, additional therapeutic and prescription drug purchases, and other treatments;

15 d. Costs for providing treatment, counseling, and rehabilitation services; and

16 e. Costs associated with providing care for children whose parents suffer
17 from opioid-related disability or incapacitation, including foster care services.

18 559. McKinsey and its clients knew, or should have known, of the risks and harms of
19 fetal opioid exposure but suppressed this information, thereby depriving doctors, women, parents,
20 scientists, and regulators of critical information. The artificial increase in supply of opioids driven
21 by McKinsey and its clients led women of child-bearing age, and pregnant people alike, to
22 become addicted, stay addicted, and, ultimately, expose their fetuses to opioids.

23 560. In particular, McKinsey was in a position to have access to Purdue's
24 comprehensive and highly-sophisticated and detailed life sciences library consisting of, for
25 instance, volumes of Company Core Data Sheets ("CCDS") (from at least 2000-2017) containing
26 whole sections with entries for fertility, pregnancy and lactation. McKinsey also was in a position
27

28 ³⁸³ National Associate of State Alcohol and Drug Abuse Directors, Inc., Neonatal Abstinence Syndrome,
<http://nasadad.wpengine.com/wp-content/uploads/2015/06/NAS-Fact-Sheet-Final.pdf> (June 2015).

1 to have access to reams of manufacturers' adverse event reports documenting a wide range of
 2 birth defects resulting from fetal opioid exposure, including brain stem malformations, digestive
 3 tract malformations, heart defects, skeletal malformations, spina bifida, and cleft palate.

4 561. McKinsey was privy to, collaborated with, and enabled internal manipulation of
 5 scientific studies related to the risks and harms posed by Purdue's opioid products. For example,
 6 over the years, language found in Purdue's warning labels and CCDS regarding potential
 7 reproductive dangers of their drugs, in particular NAS and NOWS, changed drastically. [REDACTED]

8 [REDACTED]

9 [REDACTED]³⁸⁴ [REDACTED]

10 [REDACTED]³⁸⁵ [REDACTED]

11 [REDACTED]

12 [REDACTED]³⁸⁶ By virtue of McKinsey's familiarity and work in connection with Purdue's research
 13 and development and regulatory processes, McKinsey would have been aware of changes to
 14 entries contained in Purdue's CCDS for oxycodone and other opioid products.

15 562. McKinsey could have, and should have, included warnings for the prescribing of
 16 opioid drugs during pregnancy in its opioid marketing plans.

17 **B. Harm to Plaintiffs**

18 **1. Melissa Barnwell, E.G., and C.G.**

19 563. Melissa Barnwell is the biological mother of C.G. and E.G., who were born
 20 dependent on opioids.

21 564. Beginning in 1993, Ms. Barnwell was prescribed opioids, including OxyContin,
 22 after she was struck by a motor vehicle and suffered from multiple fractures and broken bones,
 23 ongoing severe back and joint pain, fibromyalgia, and arthritis.

24 565. In 2006, during her pregnancy with C.G., Ms. Barnwell's doctors continued to
 25 prescribe her OxyContin for the management of her chronic pain. C.G. was born on June 18,
 26 2006 at Kaweah Delta Medical Center in Visalia, CA. Within two hours of birth, C.G. was

27 ³⁸⁴ See PURCHI-000572404, 1994 Archival New Drug Application. [2804]

28 ³⁸⁵ See PKY180604976, 1997 Archival New Drug Application for Oxycodone. [2804]

³⁸⁶ See PPLPC013000063753, 2000 Company Core Data Sheet, Oxycodone Hydrochloride. [2804]

1 admitted to the NICU for treatment of NOWS. C.G. was diagnosed with fetal opioid exposure
 2 and, due to her severe withdrawal symptoms, remained in the hospital until July 27, 2006. Upon
 3 discharge, C.G. required continued treatment with phenobarbital and methadone for
 4 approximately six months. As a result of her exposure to opioids in utero, C.G. suffers from club
 5 foot, hearing problems, learning and developmental delays, and social and behavioral problems.

6 566. In 2008, while pregnant with E.G., Ms. Barnwell's physicians continued to
 7 prescribe her opioids. Ms. Barnwell gave birth to E.G. on May 9, 2008 at Fresno Community
 8 Hospital in Fresno, CA. E.G. was diagnosed with NAS. Due to her severe withdrawal symptoms,
 9 E.G. required treatment with phenobarbital and methadone for three months, and she remained in
 10 the hospital until May 25, 2008. As a result of her exposure to opioids in utero, E.G. suffers from
 11 vision problems, gastrointestinal problems, learning and developmental delays, and social and
 12 behavioral problems.

13 **2. Hayden Travis Blankenship and Z.D.B.B.**

14 567. Hayden Travis Blankenship is the biological father of Z.D.B.B., who was born
 15 dependent on opioids.

16 568. Upon information and belief, Z.D.B.B.'s biological mother was prescribed a
 17 variety of opioids before and during her pregnancy with Z.D.B.B., including but not limited to
 18 hydrocodone with acetaminophen from 2012 to 2013, oxycodone with acetaminophen from 2012
 19 to 2015, and OxyContin. While pregnant with Z.D.B.B., she also used opioids obtained from the
 20 illegal diversionary market.

21 569. Z.D.B.B. was exposed to opioids in utero and was born three months prematurely
 22 on May 29, 2017 at Princeton Community Hospital in Princeton, WV. Z.D.B.B. was diagnosed
 23 with NAS at birth and was transferred to the NICU at CAMC Women and Children's Hospital in
 24 Charleston, WV. Z.D.B.B.'s medical records from the NICU show that he experienced
 25 intrauterine growth restriction, maternal methadone usage, tachypnea, respiratory distress
 26 requiring oxygen at 35%, hepatitis C, high pitched and excessive crying, increased muscle tone,
 27 myoclonic jerks, mottling, loose stools, hypertonic motor reflexes, mild tremors, excoriation,
 28 persistent NAS-related fevers, increased and abnormal respiratory rate, and difficulty feeding

1 requiring a nasogastric tube and parenteral nutrition. Today, Z.D.B.B. suffers from vision
 2 problems, respiratory issues, irritable bowel problems, chronic diarrhea and gastrointestinal
 3 problems, attention problems and inability to focus, depression, learning disabilities and cognitive
 4 delays, and social and behavioral difficulties.

5 **3. Marina Brizendine and S.B.**

6 570. Marina Brizendine is the biological mother of S.B., who was born dependent on
 7 opioids.

8 571. Ms. Brizendine was first prescribed OxyContin around 2005 for chronic pain
 9 related to a preexisting knee injury. She continued to be prescribed opioids, including OxyContin,
 10 through 2019 to manage her pain due to carpal tunnel and nerve damage in her right shoulder.

11 572. From the time she realized she was pregnant with S.B. in July 2016 until S.B.'s
 12 birth on April 8, 2017, Ms. Brizendine was prescribed and took at least 1,182 opioid pills,
 13 including OxyContin. Many of these pills were prescribed by Dr. Lawrence Peters as a part of his
 14 pain management practice. Upon information and belief, Dr. Peters was a "very high target
 15 M.D.," a class of doctors targeted by Purdue.

16 573. As a result of S.B.'s exposure to opioids in utero, she was diagnosed with NAS
 17 and spent her first three nights in the NICU. While in the NICU, she experienced tremors and
 18 hypertonia. S.B. currently suffers from developmental disabilities and hearing impairment as a
 19 result of NAS. S.B.'s ability to thrive has been severely if not permanently diminished due to in
 20 utero exposure to opioids.

21 **4. Lisa Renee Daniels and A.K.D.**

22 574. Beginning in 1993, Ms. Barnwell was prescribed opioids, including OxyContin,
 23 after she was struck by a motor vehicle and suffered from multiple fractures and broken bones,
 24 Lisa Renee Daniels is the grandmother and legal guardian of A.K.D., who was born dependent on
 25 opioids.

26 575. Upon information and belief, A.K.D.'s biological mother was prescribed and
 27 consumed a variety of opioid drugs before and during pregnancy, including OxyContin,
 28 acetaminophen with codeine, hydromorphone, naltrexone, buprenorphine, naloxone, and

1 Suboxone. She filled her prescriptions at Fruth Pharmacy in Huntington, WV and Marshall
2 Pharmacy in Huntington, WV. A.K.D.'s biological mother also obtained illicit drugs from the
3 diversionary market.

4 576. A.K.D. was born September 18, 2019. As a result of his exposure to opioids in
5 utero, he experienced NOWS, including tremors and convulsions, diarrhea, signs of excessive
6 sucking, excessively runny nose, high pitched screaming, and irritability. Today, A.K.D.
7 continues to suffer from respiratory issues, irritable bowel problems, chronic diarrhea and
8 gastrointestinal problems, growth and developmental delays, and social and behavioral
9 difficulties.

10 **5. April Hudak and H.S.**

11 577. April Hudak is the biological mother of H.S., who was born dependent on opioids.

12 578. Ms. Hudak was first prescribed opioids by her pain management physician in 2004
13 for chronic pain associated with fibromyalgia. From 2009 through 2012, she was prescribed large
14 quantities of OxyContin in combination with other opioids. In the 18-month period between
15 December 2010 and June 2012, Ms. Hudak was prescribed and took over 3,700 opioid pills. As a
16 result of her opioid prescriptions, she became dependent on opioids and eventually developed a
17 condition known as opioid use disorder.

18 579. During her pregnancy with H.S., Ms. Hudak was prescribed and consumed over
19 1,400 opioid pills. On June 6, 2012, she gave birth to H.S. in Aurora, CO. As a result of her
20 exposure to opioids in utero, H.S. was dependent upon on opioids at birth and spent the first
21 thirteen days of her life in the hospital. In order to treat her opioid dependence, H.S. was
22 administered methadone while in the NICU and after her discharge.

23 **6. Timothy Lambert, T.J.L., and M.L.**

24 580. Timothy Lambert is the biological father of T.J.L and M.L., who were born
25 dependent on opioids.

26 581. Upon information and belief, T.J.L and M.L.'s biological mother was prescribed
27 opioids both before and during each of her pregnancies. As a result, T.J.L and M.L. were exposed
28

1 to opioids in utero and were born several weeks premature by emergency C-Section due to low
2 amniotic fluid. Both were diagnosed with NAS at birth and were treated for NOWS.

3 582. T.J.L. was born on October 3, 2003 at Charleston Area Medical Center Women
4 and Children's Hospital in Charleston, WV. T.J.L. spent a month in the NICU for treatment for
5 NOWS. Following birth, T.J.L. suffered from tremors, diarrhea, high pitched screaming,
6 difficulty sleeping, and irritability. Today, he suffers from serious vision problems, attention
7 difficulties and inability to focus, learning disabilities, and cognitive delays.

8 583. M.L. was born on December 21, 2010 at Raleigh General Hospital in Beckley,
9 WV. She was treated for NOWS and continues to suffer from learning difficulties and cognitive
10 delays.

11 584. T.J.L and M.L.'s biological mother died of a drug overdose in 2017. As a result of
12 her opioid addiction, T.J.L and M.L. have been permanently deprived of their mother's comfort,
13 care, and support.

14 **7. Andria Meeder and C.M.**

15 585. Andria Meeder is the biological mother of C.M., who was born dependent on
16 opioids.

17 586. Ms. Meeder was prescribed opioids, including OxyContin, as a result of a
18 herniated discs, fibromyalgia, back and neck issues, and arthritis.

19 587. On September 1, 2015, Ms. Meeder gave birth to C.M. at Mercy Hospital in
20 Buffalo, NY. As a result of his exposure to opioids in utero, C.M. experienced hypertonicity,
21 tremors and convulsions, diarrhea, vomiting, and his medical records detailed elevated scores on
22 the Finnegan Scale. As part of his treatment for NOWS, he was administered methadone for two
23 weeks beginning the day after he was born. Today, C.M. suffers from autism, ADHD, and
24 developmental delays, and his quality of his life has been vastly diminished due to fetal opioid
25 exposure.

26 **8. Jacqueline Ramirez and R.R.**

27 588. Jaqueline Ramirez is the biological mother of R.R, who was born dependent on
28 opioids.

589. Ms. Ramirez was prescribed opioids, including Duragesic, after a 2001 leg injury. In 2005, while still using Duragesic, Ms. Ramirez gave birth to R.R. Upon birth, R.R. experienced severe withdrawal symptoms as a consequence of fetal opioid exposure. R.R.'s medical records report incredibly high withdrawal symptoms including four consecutive scores of 14 on the Finnegan Scale. To treat him for opioid withdrawal syndrome, R.R. was administered medication assisted therapy, including methadone hydrochloride, phenobarbital, and hydrocortisone. As a result of his exposure to opioids in utero, R.R suffers from an Arnold-Chiari brain malformation, sensory problems, digestive problems, hearing and vision issues, cognitive and developmental delays, and social and behavioral problems.

9. Beverly and Andrew Riling and A.R.

590. Beverly and Andrew Riling are the grandparents and legal guardians of A.R., who was born dependent on opioids.

591. Upon information and belief, throughout her pregnancy, A.R.'s biological mother used OxyContin, Percocet, and other opioids that she obtained both legally from prescriptions written for her by doctors and illegally, through the diversion of pills from prescriptions written for her parents.

592. A.R. was born on February 25, 2007. A.R. was exposed to opioids in utero and began his life suffering from the short-term effects of NOWS. Today, A.R. continues to suffer from the persistent effects of prenatal exposure to opioids, including difficulties with attention, mood, and cognition.

10. Julieann Valdez, J.V., and M.V.

593. Julieann Valdez is the biological mother of J.V. and M.V., who were born dependent on opioids.

594. Ms. Valdez was first prescribed opioids in 2002 due to back and leg pain caused by a car accident and arthritis. She received OxyContin prescriptions between 2009 and 2010.

595. Ms. Valdez remained on prescription opioids throughout her pregnancy with J.V., resulting in fetal opioid exposure. When J.V. was born in West Jordan, UT in 2012, he was diagnosed with NAS. J.V. also experienced respiratory distress, growth delays, and jaundice and

1 failed to thrive. He remained in NICU for two weeks while he was treated with morphine and
2 phenobarbital. Upon discharge, J.V. was sent home with phenobarbital. Throughout childhood, he
3 has experienced numerous infections, including ear infections, throat infections, skin infections,
4 and pneumonia. J.V. has also been diagnosed with oppositional defiance disorder, conduct
5 disorder, and ADHD.

6 596. During her pregnancy with M.V., Ms. Valdez continued to be prescribed opioids,
7 but she switched to methadone when she learned she was pregnant. M.V. was born in Carson
8 City, NV. At birth, M.V. was diagnosed with NAS and was treated for Nows for nine days. He
9 experienced tremors, convulsions, high pitched cry, frequent sneezing, and constant diaper rash.
10 M.V. is currently three years old, and Ms. Valdez has noticed some developmental delays in him.

11 **11. Shelly Whittaker, G.O., N.G., and E.W.**

12 597. Shelly Whittaker is the biological mother of E.W., N.G., and G.O., who were born
13 dependent on opioids.

14 598. Ms. Whittaker was first prescribed opioids, including OxyContin for the treatment
15 of systemic lupus erythematosus, fibromyalgia, and rheumatoid arthritis. She remained on
16 prescription opioids during her pregnancies with all three of her children and was never advised
17 that her use of these drugs could harm her children.

18 599. During her pregnancy with G.O., Ms. Whittaker was prescribed opioids for
19 treatment of her lupus and arthritis. Ms. Whittaker gave birth to G.O. at Poudre Valley Hospital in
20 Fort Collins, CO on June 22, 2007. G.O. began to exhibit signs and symptoms of opioid
21 withdrawals when Ms. Whittaker stopped nursing him. G.O. shook violently and exhibited
22 irritability, high-pitched crying, had difficulty sleeping, swallowing and eating, loss of appetite,
23 diarrhea, tremors, and convulsions. G.O. suffers from ADHD, depression, and insomnia. He also
24 has problems with anger management and experiences social anxiety, which requires him to be
25 homeschooled. He is receiving ongoing therapy for these conditions. G.O. has also been
26 diagnosed with cognitive delays, and he is currently functioning two years behind grade level in
27 school.
28

1 600. During her pregnancy with N.G., Ms. Whittaker was prescribed opioids for
2 treatment of her lupus and arthritis. Ms. Whittaker gave birth to N.G. at Poudre Valley Hospital in
3 Fort Collins, CO on March 2, 2010. As a result of N.G.'s exposure to opioids in utero, he was
4 diagnosed with NOWS and spent one week in the NICU, where he was prescribed morphine to
5 treat the symptoms of his withdrawals. Around the time of his birth, he experienced irritability,
6 high pitched crying, loss of appetite, difficulty swallowing, difficulty sleeping, excessive
7 vomiting and diarrhea, tremors, and convulsions. N.G. has been diagnosed with behavioral
8 problems, frequently gets into fights, and has other disciplinary problems at school.

9 601. While Ms. Whittaker was previously prescribed Suboxone, her doctors switched
10 her to Subutex while she was pregnant while was pregnant with E.W. E.W. was born at Poudre
11 Valley Hospital in Fort Collins, CO on June 29, 2013. Around the time of his birth, E.W.
12 experienced irritability, high pitched crying, difficulty sleeping, excessive diarrhea, runny nose,
13 heavy sweating, tremors, and convulsions. Although E.W. has not been diagnosed with any
14 cognitive delays, he has had difficulty keeping up in school and has experienced behavioral
15 problems.

16 **12. Anita Whigham and J.C.**

17 602. Anita Whigham is the adoptive mother of J.C., who was born dependent on
18 opioids.

19 603. J.C.'s biological mother was first prescribed opioids by her pediatrician for back
20 pain when she was 17 or 18 in approximately 1997 or 1998, and she became dependent on
21 opioids. In the 18-month period between January 2008 and J.C.'s birth in August 2010, J.C.'s
22 biological mother was prescribed and consumed over 3,400 opioid pills, including OxyContin.
23 She was prescribed and took over 1,400 of these pills during her pregnancy with J.C. She
24 continued to take prescription opioids through August 9, 2010, when J.C. was born in Milwaukee,
25 WI.

26 604. Following J.C.'s birth, he was diagnosed with NAS as a result of his prolonged
27 exposures to opioids in utero. J.C. experienced NOWS and spent the first month of his life in the
28 NICU. There, he was administered methadone for over thirty days to treat his opioid dependence.

1 J.C. experienced developmental delays and could not walk until 20 months, did not begin to
2 speak until 24 months, and was not toilet trained until age five. He has been diagnosed on the
3 autism spectrum and with ADHD. Despite intensive speech, occupational and physical therapy,
4 his disabilities persist, and due to his inability to thrive, it is highly unlikely that J.C. will ever be
5 able to live independently.

6 605. J.C. was a ward of the State of Wisconsin until he was nine years old, at which
7 point Ms. Whigham adopted him.

8 **13. Cynthia Woolwine, B.W., and E.G.W.**

9 606. Cynthia Woolwine is the biological mother of B.W. and E.G.W., who were born
10 dependent on opioids.

11 607. Ms. Woolwine was a medic for around twenty years. During the course of her
12 employment, she was regularly required to lift patients, and as a result, she developed carpal
13 tunnel and compression fractures of the C4 and C5 vertebrae. She was prescribed OxyContin and
14 large quantities of other opioids, including Lortabs, Endocet, Percocet, Nucynta, and oxycodone,
15 for her injuries beginning in 2003 and became opioid dependent. Due to the abundance of illicit
16 drugs in West Virginia, she later began buying pills from the street to satisfy her addiction.

17 608. B.W. was born on October 23, 2003 at Raleigh General Hospital in Beckley, WV.
18 B.W. was born premature and small for her gestational age. After birth, B.W. remained in the
19 hospital for a week as she was administered medication assisted therapy as treatment for NOWS.
20 She continues to suffer from a lazy eye, digestive issues, cognitive delays, and aggression.

21 609. Two months into her pregnancy with E.G.W., Ms. Woolwine was transitioned to
22 Suboxone for medication assisted therapy and continues to take Suboxone today. E.G.W. was
23 born premature on November 14, 2012 by emergency C-section also at Raleigh General Hospital.
24 She weighed less than five pounds at birth and exhibited many symptoms of NAS, including
25 difficulty swallowing, muscle stiffness, and tremors. E.G.W. continues to have issues with her
26 vision. She also experiences acid reflux problems, which cause her to have difficulty eating and
27 gaining weight. She is currently nine years old but only around 40 pounds. E.G.W. was behind
28

developmentally but has progressed closer to her grade level in recent years. However, E.G.W. still struggles with ADHD and has trouble focusing at school and in social settings.

VIII. CLAIMS FOR RELIEF

A. Multiple States' Plaintiffs

1. Negligence (All Plaintiffs)

610. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

611. McKinsey, through its work with Purdue and other opioid supply chain clients, owed Plaintiffs a duty to not expose Plaintiffs to an unreasonable risk of harm.

612. McKinsey, through its work with Purdue and other opioid supply chain clients, owed a duty of care to the Plaintiffs pursuant to which it would not encourage the over-marketing and over-prescribing of a controlled substance known at the time to be addictive—among other harmful effects—and known at the time to be a threat to public health.

613. It also owed such a duty pursuant to the Corporate Integrity Agreement as a “Covered Person.”

614. In violation of this duty, for years McKinsey devised, initiated, and enabled and assisted, in conjunction with Purdue and other opioid supply chain clients, sales and marketing campaigns, including Project Turbocharge, that would dramatically increase the amount of OxyContin and other opioids prescribed and distributed to Plaintiffs’ communities (and nationwide), including to women of childbearing age and pregnant women alike. In the process, McKinsey continually devised misleading claims regarding opioids, including OxyContin, as part of their efforts to get healthcare providers, including the Minor Plaintiffs’ biological mothers’ healthcare providers, to write more and more opioids prescriptions, while ignoring, concealing, and downplaying adverse events reports and publicly-available medical literature describing concerns with opioid use during pregnancy.

615. Given the knowledge McKinsey and its clients possessed about the risks of opioid use during pregnancy, it was reasonably foreseeable that McKinsey’s actions and omissions

1 would result in the harm to Plaintiffs described herein. Specifically, McKinsey and its clients
2 knew, or should have known of the risks of NAS and NOWS and the resulting medical
3 complications.

4 616. As a direct and proximate result of McKinsey's negligent conduct, the Minor
5 Plaintiffs' biological mothers were prescribed and became dependent upon OxyContin and other
6 opioids that, during pregnancy, led to the Minor Plaintiffs' exposure to opioids in utero.
7 Following birth, as a direct and proximate result of McKinsey's negligent conduct, the Minor
8 Plaintiffs' suffered from, and continue to suffer from, an array of harmful effects arising from
9 sustained opioid exposure as described herein.

10 617. There is moral, ethical and legal blame attached to McKinsey as a result of the
11 terrible injuries and suffering their misconduct caused, including the damage to Plaintiffs.

12 618. Public policy supports finding a duty of care in this circumstance, and a finding of
13 a duty of care on McKinsey will also deter McKinsey from engaging in such behavior in the
14 future.

15 619. Further, the conduct alleged against McKinsey in this Complaint was despicable
16 and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights,
17 constituting oppression, for which McKinsey must be punished by punitive and exemplary
18 damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard
19 for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is
20 outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An
21 officer, director, or managing agent of McKinsey personally committed, authorized, and/or
22 ratified the outrageous and wrongful conduct alleged in this Complaint.

23 620. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not
24 have happened in the ordinary course of events if McKinsey had used due care commensurate to
25 the dangers involved in the distribution and dispensing of controlled substances.

1 2. **Negligent Misrepresentation**
2 **(All Plaintiffs)**

3 621. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth
4 herein, and further allege as follows:

5 622. McKinsey, through its work with Purdue and other opioid supply chain clients,
6 owed Plaintiffs a duty to not expose Plaintiffs to an unreasonable risk of harm.

7 623. McKinsey, through its work with Purdue and other opioid supply chain clients,
8 owed a duty of care to the Plaintiffs pursuant to which it would not encourage the over-marketing
9 and over-prescribing of a controlled substance known at the time to be addictive—among other
10 harmful effects—and known at the time to be a threat to public health.

11 624. It also owed such a duty pursuant to the Corporate Integrity Agreement as a
12 “Covered Person.”

13 625. McKinsey, in the course of its business with Purdue and other opioid supply chain
14 clients, failed to exercise reasonable care or competence when obtaining, evaluating, and
15 communicating false information regarding OxyContin and other opioids that McKinsey knew
16 would be used for the guidance by women of childbearing age and pregnant people, including but
17 not limited to the Minor Plaintiffs’ biological mothers and their healthcare providers.

18 626. McKinsey knew or should have known that the false and misleading information
19 was material to the Minor Plaintiffs’ biological mother’s healthcare providers’ decision to
20 prescribe opioids to patients. McKinsey intended that such statements be relied upon to encourage
21 additional opioid prescriptions.

22 627. As a direct and proximate result of McKinsey’s negligent misrepresentations, the
23 Minor Plaintiffs’ biological mothers were prescribed and suffered addiction from OxyContin and
24 other opioids, which led to the Minor Plaintiffs’ exposure to opioids in utero and, upon birth,
25 causing them to suffer from the harmful effects sustained as a result of opioid exposure as
26 described herein.

27 628. There is moral, ethical and legal blame attached to McKinsey as a result of the
28 terrible injuries and suffering their misconduct caused, including the damage to Plaintiffs.

629. Public policy supports finding a duty of care in this circumstance, and a finding of a duty of care on McKinsey will also deter McKinsey from engaging in such behavior in the future.

630. Further, the conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. McKinsey's conduct was and is outrageous, done with malice and evidenced reckless indifference to the interests of Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

631. Minor Plaintiffs are without fault, and the injuries to Minor Plaintiffs would not have happened in the ordinary course of events if McKinsey had used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

3. Fraud (Actual and Constructive) and Deceit (All Plaintiffs)

632. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

633. McKinsey committed fraud by acting to conceal and advising the concealment of the true dangers of opioids and Purdue's prior and ongoing misconduct while working to increase sales of opioids through its work for Purdue and others, and concealing all of this information from regulators, the public, and Plaintiffs. McKinsey made, and caused to be made, false representations to the Minor Plaintiffs' biological mothers' healthcare providers and/or omitted material facts, regarding the risks, efficacy, and medical necessity of opioids generally, and Purdue's opioids specifically. McKinsey knew these representations were false, made recklessly without knowledge of the truth, and/or had no reasonable ground for believing such representations or assertions, in spite of its capability to acquire information disputing and

1 debunking many of the representations. Specifically, McKinsey knowingly and/or recklessly
2 engaged in the following, or caused its opioid supply chain clients to engage in the following:

3 a. Downplaying the substantial risks of addiction and other side effects of
4 opioids generally, and Purdue's opioids specifically, including crafting Purdue's marketing plan
5 to affirmatively state in sales calls and other marketing channels that Purdue's drugs were not as
6 addictive or prone to abuse as they truly are; stating that classic signs of addiction were actually
7 an indication of "pseudoaddiction" requiring administration of additional opioids, and omitting
8 the high risks of addiction actually present;

9 b. Overstating the efficacy of opioids generally, and Purdue's opioids
10 specifically, including making false statements regarding the effectiveness of the drugs for
11 treating specific subsets of the patient population and their ability to improve patient function;

12 c. Misrepresenting the medical usefulness and necessity of opioids generally,
13 and Purdue's opioids specifically, including affirmatively marketing these drugs for off-label uses
14 without solicitation and not in response to questions from healthcare providers; and

15 d. Downplaying the substantial and known risks and dangers associated with
16 opioid use during pregnancy, including misleading women of childbearing age thereby exposing
17 countless children to opioids in utero.

18 634. McKinsey, having chosen to craft the marketing plans used by Purdue and other
19 opioid supply chain clients and to make representations to healthcare providers regarding opioids,
20 were under a duty to disclose the whole truth, and to not disclose partial and misleading truths.

21 635. McKinsey and its opioid supply chain clients' misrepresentations and omissions
22 had a tendency to deceive others, violate public confidence, undermine doctor-patient trust,
23 disrupt the mother/child dyad, and/or injure public interests.

24 636. McKinsey intended healthcare providers, including the Minor Plaintiffs' biological
25 mother's healthcare providers, to rely upon it and its clients' false and misleading assertions
26 regarding the risks, efficacy, and medical necessity of opioids to increase the number of opioid
27 prescriptions made by healthcare providers.
28

637. Healthcare providers, including the Minor Plaintiffs' biological mothers' healthcare providers, did in fact rely on these false representations and omissions. As a result of their reliance, these healthcare providers prescribed opioids, often unnecessarily or in unnecessarily large quantities or high doses, to Minor Plaintiffs' biological mothers, including while they were of childbearing age or pregnant.

638. There is moral, ethical and legal blame attached to McKinsey as a result of the terrible injuries and suffering their misconduct caused, including the damage to Plaintiffs.

639. McKinsey acted with knowledge and willful intent, with reckless disregard for the rights of others, and/or intentionally and with malice towards others including the Minor Plaintiffs and their biological mothers.

640. Further, the conduct alleged against McKinsey in this Complaint was despicable and subjected Plaintiffs to cruel and unjust hardship in conscious disregard of their rights, constituting oppression, for which McKinsey must be punished by punitive and exemplary damages in an amount according to proof. McKinsey's conduct evidences a conscious disregard for the safety and welfare of others, including Plaintiffs. An officer, director, or managing agent of McKinsey personally committed, authorized, and/or ratified the outrageous and wrongful conduct alleged in this Complaint.

4. Civil Conspiracy/Joint and Several Liability (All Plaintiffs)

641. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

642. Throughout decades of McKinsey and Purdue working collaboratively, they agreed, aided, and abetted one another in committing numerous unethical, illegitimate and unlawful acts related to the regulatory approval process and the research and development process, as well as to the sales and marketing of Purdue's opioid products. McKinsey and Purdue also agreed, aided, and abetted one another in using illegitimate and unlawful means to commit lawful acts as part of these sales and marketing efforts.

1 643. Purdue was neither the first, nor the last, opioid manufacturer with whom
2 McKinsey conspired and collaborated to unlawfully drive opioid profits. McKinsey occupies the
3 proverbial “cat-bird seat,” from which it drove and oversaw a notional health crisis that has, to
4 date, caused hundreds of thousands of babies to be born dependent upon opioids and suffering
5 from NOWS and the many other effects of in utero exposure to opioids.

6 644. Numerous opioid manufacturers—including Purdue, Janssen, Endo, and others
7 alleged herein— worked diligently with McKinsey in the marketing and sale of opioids as
8 described in this Complaint. Alone and in combination, they engaged in a conspiracy to
9 illegitimately and unlawfully increase sales of opioids and grow their respective shares of the
10 prescription painkiller market through repeated and systematic pattern of omissions and
11 misrepresentations concerning the safety and efficacy of opioids for treating long-term chronic
12 pain, including during pregnancy.

13 645. To increase the demand illegitimately and unlawfully for opioids and thereby
14 increase profits, McKinsey and its co-conspirators set aside their knowledge of the harmful
15 effects of fetal opioid exposure to the detriment of countless children suffering from in utero
16 exposure to opioids. To accomplish their mutually beneficial goals, McKinsey assumed the role
17 of a go-between to its various opioid supply chain clients while, at the same time, overseeing
18 coordination of the deceptive marketing and sales strategies being implemented by these
19 companies. Through McKinsey and also via their own personal relationships, each of the
20 members of the conspiracy had the opportunity and the motive to formulate and undertake actions
21 in furtherance of their common purpose: deliberately concealing and misrepresenting material
22 information to prescribers and to Plaintiffs to increase sales of addictive and dangerous drugs as
23 well as to increase the bottom line of each member.

24 646. In the alternative, the conspiracy existed between just McKinsey and Purdue, each
25 of them working together to unlawfully increase sales of opioid and thereby grow Purdue’s share
26 of the prescription painkiller market through, for instance, repeated and systematic
27 misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain,
28 including during pregnancy. McKinsey knew that Purdue’s marketing of its opioids was

1 illegitimate as well as illegal, and that Purdue was in many respects responsible for an NAS
2 epidemic. Despite these facts and circumstances, McKinsey continued to leverage and exploit the
3 knowledge it had gained from its work with other opioid manufacturers and, with respect to
4 Purdue, McKinsey joined forces to turbocharge the opioids market and profit from the resulting
5 crisis.

6 647. Among the implementing regulations to the Controlled Substances Act is the
7 requirement that “[e]very person who manufactures, distributes, dispenses, imports, or exports
8 any controlled substance,” including opioids, become a “registrant.” *See* 21 U.S.C. § 823(a)-(b);
9 21 C.F.R. § 1301.11(a). CSA registrants, including opioid manufacturers and distributors, must
10 maintain a system to (i) identify and report suspicious orders, including identification of orders of
11 unusual size, or frequency, or orders deviating from its normal pattern as well as (ii) maintain
12 effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. §
13 1301.74(b).

14 648. Despite its lawful duties, McKinsey and its co-conspirators engaged in a scheme
15 with the shared, overarching purpose of materially expanding prescription opioid use by altering
16 the medical community’s opioid prescribing practices through repeated fraudulent statements and
17 misrepresentations, and by concealing scientific entries and conclusions surrounding known
18 harmful effects of fetal opioid exposure, such as NOWS and an ever-widening list of
19 malformations, defects, and disorders. The conspiracy was sophisticated, well-developed, and
20 fraudulent, and it was designed to increase the prescription rate for opioid medications the co-
21 conspirators know are regulated dangerous substances that, also, are highly addictive and, during
22 pregnancy, transmitted to fetuses for no medical reason or benefit. At all relevant times,
23 McKinsey was aware of its own conduct as well as the ongoing conduct of its co-conspirators,
24 making McKinsey an active, knowing, and willing participant in the misconduct. In return for
25 performing work responsible for turbocharging sales and distribution of prescription opioids,
26 McKinsey was handsomely rewarded in the form of substantial payments from each co-
27 conspirator.
28

649. The conspiracy devised, implemented, and conducted by McKinsey and its co-conspirators was a common course of conduct designed to ensure that the co-conspirators unethically, illegitimately, and unlawfully increased their sales and profits by, for instance, concealing scientific entries and conclusions surrounding known harmful effects of fetal opioid exposure, such as NOWS and ever-widening list of malformations, defects, and disorders. McKinsey and its co-conspirators acted together for a common purpose and with the intention of carrying out and perpetrating the common scheme.

650. McKinsey and its co-conspirators were each willing participants in the conspiracy, had a common purpose and interest in the object of the conspiracy, and functioned within a structure designed to effectuate the conspiracy's purpose.

651. McKinsey occupied a pivotal position in the opioid crisis by serving as a clearinghouse for critical prescriber information. As a clearinghouse, it also possessed knowledge and information regarding an industry-wide practice of suppressing information concerning risks of fetal opioid exposure that, here, proximately caused harm to the Plaintiffs by depriving doctors, women, mothers, scientists and government regulators alike, from access to critical information that, if known, would have directly impacted decisions placed upon the doctors and mothers and compelled many, if not all, not to prescribe nor use opioids during pregnancy.

652. As a result of the concerted action between the Purdue, other opioid supply chain clients, and McKinsey, Plaintiffs have suffered damages.

653. Purdue, other companies in the opioids supply chain, and McKinsey are jointly and severally liable for the results of their concerted efforts.

5. Civil Aiding And Abetting (All Plaintiffs)

654. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

655. McKinsey gave substantial assistance and encouragement to Purdue, the Sacklers, and other opioid supply chain clients regarding conduct McKinsey knew to be tortious and/or in violation of a duty owed by Purdue, the Sacklers, and other opioid supply chain clients to third

persons, including Plaintiffs. McKinsey assisted and encouraged Purdue and other opioid supply chain clients over many years to commit unlawful acts related to the sales and marketing of opioid products that McKinsey knew to be misleading and in violation of a reasonable standard of care. McKinsey gave substantial assistance and/or encouragement to Purdue and other opioid supply chain clients to use unlawful means to commit unlawful acts as part of these marketing efforts and sales.

656. Further, McKinsey gave substantial assistance and/or encouragement to Purdue and other opioid supply chain clients to take actions that violated state laws, including but not limited to public nuisance and statutory prohibitions, through McKinsey's misleading and predatory marketing campaign.

657. McKinsey's support was a substantial factor in causing harm to third parties, including Plaintiffs.

658. Plaintiffs were damaged as described herein as a result of the specific conduct that McKinsey encouraged and substantially assisted in.

6. Common Law Public Nuisance (All Plaintiffs)

659. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

660. Section 821B of the Restatement (Second) Torts defines a "public nuisance" as "an unreasonable interference with a right common to the general public."

661. McKinsey, though its work with Purdue and other opioid supply chain clients, has created and continues to perpetuate and maintain a public nuisance to Plaintiffs' communities through the massive distribution of highly addictive, commonly abused prescription painkillers known as opioids.

662. McKinsey's conduct, including its misrepresentations and omissions regarding opioids generally, and Purdue's opioids specifically, fueled an opioid epidemic within the Plaintiffs' communities that constitutes a public nuisance. McKinsey and Purdue knowingly

1 exacerbated a condition that affects entire municipalities, towns, and communities, and has
2 injured the Minor Plaintiffs specially as described herein.

3 663. McKinsey's conduct, including its misrepresentations and omissions regarding
4 opioids generally, and Purdue's opioids specifically, constitutes unlawful acts and/or omissions of
5 duties, that annoy, injure, or endanger the comfort, repose, health, and/or safety of others.

6 664. As a direct and proximate result of the wrongful conduct of McKinsey as set forth
7 herein, McKinsey negligently, intentionally, and/or unreasonably interfered with the rights of
8 citizens of the Plaintiffs' communities, including the Minor Plaintiffs' right to be free from
9 unwarranted injuries, addictions, diseases, sicknesses, overdoses, criminal actions.

10 665. McKinsey's actions were, at the very least, a substantial factor in opioids
11 becoming widely available and widely used. McKinsey's actions were, at the very least, a
12 substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the
13 treatment of chronic pain, including during pregnancy. Without McKinsey's actions, opioid use,
14 misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that
15 now exists would have been averted or much less severe.

16 666. McKinsey has caused ongoing harms and inconveniences to those who have been
17 exposed to the risk of addiction to opioids, who have become addicted, and/or have suffered other
18 adverse consequences from the use of the addictive opioids, and have been adversely affected by
19 the addiction and abuse of others in their communities from the highly addictive, prescription
20 pain medication distributed pursuant to McKinsey's ill-conceived strategies.

21 667. In addition to the harm suffered by the community at large, the Minor Plaintiffs
22 have suffered special damages due to their exposures to opioids in utero.

23 668. McKinsey also has a duty to abate the nuisance caused the by prescription opioid
24 epidemic.

25 669. The public nuisance created, perpetuated, and maintained by McKinsey can be
26 abated and further recurrence of such harm and inconvenience can be abated.

27 670. McKinsey has failed to abate the nuisance it created.
28

1 671. Plaintiffs seek an order providing for abatement of the public nuisance that
2 McKinsey created or assisted in the creation of, and enjoining McKinsey from future conduct
3 creating a public nuisance.

4 672. Plaintiffs seek damages from McKinsey to pay for the costs to permanently
5 eliminate the hazards to public health and safety and abate the public nuisance.

6 673. As a direct result of McKinsey's conduct, Plaintiffs have suffered actual injury and
7 economic damages including, but not limited to, the harmful effects of opioids in utero and the
8 costs associated with continuing medical care as a result.

9 674. McKinsey is liable to Plaintiffs for the costs borne by Plaintiffs as a result of the
10 opioid epidemic and for the costs of abating the nuisance created by McKinsey.

11 **7. Negligence Per Se**
12 **(All Plaintiffs)**

13 675. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth
14 herein, and further allege as follows:

15 676. A presumption of negligence (negligence per se) is established where a
16 defendant's negligence involves the violation of a statute or regulation, a plaintiff is within the
17 class of persons that the statute or regulation was designed to protect, and the violation is a
18 substantial factor in the plaintiff's harm.

19 677. McKinsey enabled, contributed to, as well as aided and abetted violations of the
20 Controlled Substances Act, as well as state-specific controlled substances laws. McKinsey also
21 violated state-specific statutory nuisance laws, as identified elsewhere in this Complaint.

22 678. Plaintiffs are in the class of persons the statutes were designed to protect. The
23 Controlled Substances Act and analogous state laws were enacted in part to protect Plaintiffs
24 from the harm traceable to unregulated distribution of dangerous, addictive substances. State
25 nuisance statutes were enacted in part to shield persons like Plaintiffs from the costs of public
26 nuisances like the one alleged herein.

1 **B. California Plaintiffs**

2 679. The California Plaintiffs are Melissa Barnwell on behalf of her natural minor
3 children, E.G. and C.G., and Jacqueline Ramirez on behalf of her natural minor child, R.R.

4 **1. Nuisance (Cal. Civ. Code §§ 3479 et seq.)**

5 680. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth
6 herein, and further allege as follows:

7 681. For the reasons set forth in the Common Law Nuisance cause of action, the
8 California Plaintiffs have a cause action for the special damages they have suffered from the
9 public and/or private nuisance created by McKinsey pursuant to Cal. Civil Code §§ 3479 *et seq.*

10 **C. West Virginia Plaintiffs**

11 682. The West Virginia Plaintiffs are Hayden Travis Blankenship, on behalf of his
12 natural minor child, Z.D.B.B.; Lisa Renee Daniels on behalf of her legally adopted minor child,
13 A.K.D.; Timothy Lambert, on behalf of his natural minor children, T.J.L and M.L.; Beverly and
14 Andrew Riling, on behalf of their legally adopted minor child, A.R.; and Cynthia Woolwine, on
15 behalf of her natural minor children, B.W. and E.G.W.

16 **1. Joint Venture Liability**

17 683. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth
18 herein, and further allege as follows:

19 684. McKinsey involves itself deeply in the implementation of advice to its clients.
20 McKinsey and its clients created a vehicle in which directly share in the success stemming from
21 the implementation of McKinsey's advice such that relationship between McKinsey and its
22 clients is a joint venture. McKinsey and its opioid supply chain clients/co-conspirators conducted
23 themselves as a single business enterprise for profit in which they combine their property, money,
24 effects, skill, or knowledge.

25 685. McKinsey's clients make available to McKinsey consultants some of their most
26 treasured and guarded property: intellectual property in the form of proprietary trade secret and
27 scientific data. McKinsey, while under an obligation to maintain its clients' confidentiality and
28

1 trade secret protection, is free to use this intellectual property as part of its knowledge base in
2 consulting with other opioid supply chain clients.

3 686. As alleged herein, McKinsey did not merely write memos containing sage advice;
4 McKinsey also deployed its skill and knowledge by completely embedding its employees within
5 the operations of opioid supply chain clients.

6 687. McKinsey prides itself on providing transformational advice and “doing real work
7 and being jointly responsible for the success.”

8 688. Not only was McKinsey “jointly responsible” for its clients’ success but McKinsey
9 maintained the under the auspices of the McKinsey Investment Office, a private hedge fund for
10 the benefit of its partners that enabled McKinsey partners to enjoy direct financial benefits from
11 the success of McKinsey’s clients/joint venturers.

12 689. As alleged further herein, MIO provided the vehicle through which McKinsey
13 heavily invested in the opioid industry and thus stood to gain financially from the continuation of
14 the opioid crisis.

15 690. By reaping financial gains beyond the usual consulting fees, McKinsey crossed the
16 line from vendor to joint venturer because during the years when McKinsey implemented
17 strategies that propelled opioid sales, “MIO partners held stakes in companies that profited from
18 increased [opioid] usage.”

19 691. McKinsey is jointly and severally with its opioid supply chain clients as a result of
20 their joint venture from which Plaintiffs suffered damages.

21 **2. Tort of Outrage**

22 692. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth
23 herein, and further allege as follows:

24 693. McKinsey’s actions contributed to the targeting of doctors in a manner certain to
25 drive inappropriate prescriptions to Minor Plaintiffs’ biological mothers, certain to drive opioids
26 to the diversionary market accessed by Minor Plaintiffs’ biological mothers, and certain to enable
27 the opioid industries’ concealment of known long-term effects of fetal opioid exposure.
28

694. McKinsey's conduct pled herein was so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency and to be regarded as atrocious and utterly intolerable in a civilized community.

695. The conduct of McKinsey as set forth herein is so outrageous that it rises to the level of a tort of outrage from which the Plaintiffs have derived special damages.

3. Negligent Infliction of Emotional Distress

696. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

697. McKinsey's negligent conduct as pled herein fostered the opioid crisis in a manner which specifically led to the Plaintiffs' fetal opioid exposure.

698. Given the well-known physical impacts of fetal opioid exposure and the well-known long-term neuro-behavioral impacts of fetal opioid exposure, the Plaintiffs' emotional distress resulting from fetal opioid exposure was the foreseeable result of McKinsey's negligent conduct.

4. Medical Monitoring

699. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein, and further allege as follows:

700. Plaintiffs assert a claim for Medical Monitoring under West Virginia based on Minor Plaintiffs' exposure to opioids, a known toxic substance, at a concentration higher than expected for the general population.

701. Such exposure was proximately caused by the McKinsey's tortious activities as pled herein.

702. Plaintiffs face a lifetime of latent, dread medical and emotional conditions resulting from in utero exposure to opioids including but not limited to: brain damage, heart valve malformations, muscular-skeletal developmental disorders, speech and language disorders, cognitive developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders, increased risk of addiction, and other effects set forth in this Complaint.

703. Plaintiffs will benefit from medical monitoring for the aforementioned medical and emotional conditions because testing and continued monitoring will bring to light the onset of these medical and emotional conditions so that treatment and intervention may begin at the earliest point possible.

704. Plaintiffs will also benefit from a medical monitoring program featuring an epidemiological component that collects and analyzes medical monitoring results. Such a program will enable heretofore unrecognized latent, dread diseases that may be associated with in utero opioid exposure to be identified so that treating professionals may better care for Plaintiffs and so that medical professionals engaged in the research and development of new treatment will have access to a broader universe of data.

705. Plaintiffs will require ongoing care for the aforementioned conditions which are known to result from in utero exposure to opioids including but not limited to medical care, psychiatric care, psychological care, physical therapy, cognitive therapy, and speech therapy.

706. The harm visited upon minor Plaintiffs is irreparable.

707. Given the immense wealth of McKinsey, such injunctive and equitable relief presents no undue burden or irreparable damage to McKinsey.

IX. PRAYER FOR RELIEF

Plaintiffs seek all legal and equitable relief permitted by law, including:

1. Pain and suffering, past, present, and future;
2. Medical expenses, past, present, and future;
3. Loss of earning capacity;
4. Punitive and/or exemplary damages;
5. Pre- and post-judgment interest;
6. Injunctive/equitable relief; and
7. Attorneys' fees and costs.

X. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

1 Dated: December 6, 2021

Respectfully submitted,

2 By: /s/ Scott R. Bickford

3 Scott R. Bickford

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Pursuant to PTO 2:**

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